(1) CAMBRIDGESHIRE COUNTY COUNCIL

(2) [ ]

SERVICE AGREEMENT relating to

the provision of community pharmacy services

THIS AGREEMENT is dated **[DATE]**

PARTIES

(1) **CAMBRIDGESHIRE COUNTY COUNCIL** of Shire Hall Castle Hill Cambridge CB3 0AP (**Authority**).

(2) **[FULL COMPANY NAME]** incorporated and registered in England and Wales with company number **[NUMBER]** whose registered office is at **[REGISTERED OFFICE ADDRESS]** (**Service Provider**).

BACKGROUND

(A) The Authority sought tenders for the provision of Community Pharmacy services in accordance with the Dynamic Purchasing System established on [ ] ("DPS") to comply with Section 2B of the National Health Act 2006, Section 12 of the Health and Social Care Act 2012 and the Local Authorities (Public Health Functions and Entry to Premises by Local Healthwatch Representatives) Regulations 2013.

(B) The Service Provider is appointed to the DPS and has submitted a tender to the Authority for the supply of those services and in accordance with the procedure set out in the DPS, the Authority has accepted the Service Provider's tender.

(C) The Authority appoints the Service Provider and the Service Provider accepts the appointment to provide the services in accordance with the provisions of this agreement.

AGREED TERMS

1. DEFINITIONS AND INTERPRETATION

1.1 The definitions and rules of interpretation in this clause apply in this agreement.

Achieved Service Levels: in respect of any Service in any measurement period, the standard of performance actually achieved by the Service Provider in the provision of that Service in the measurement period in question (calculated and expressed in the same way as the Service Level for that Service is calculated and expressed in Schedule 2).

Applicable Law: the laws of England and Wales and the European Union and any other laws or regulations, regulatory policies, guidelines or industry codes which apply to the provision of the Services.

Associated Company: any holding company from time to time of the Service Provider and any subsidiary from time to time of the Service Provider, or any subsidiary of any such holding company.

Authorised Representatives: the persons respectively designated as such by the Authority and the Service Provider, the first such persons being set out in Schedule 5.

Authority Assets: any materials, plant or equipment owned or held by the Authority and provided by the Authority for use in providing the Services.

Authority's Premises: the premises identified in Schedule 10 and which are to be made available for use by the Service Provider for the provision of the Services on the terms set out in this agreement.

Best Industry Practice: the standards which fall within the upper quartile in the relevant industry for the provision of comparable services which are substantially similar to the Services or the relevant part of them, having regard to factors such as the nature and size of the parties, the service levels, the term, the pricing structure and any other relevant factors.

Bribery Act: the Bribery Act 2010 and any subordinate legislation made under that Act from time to time together with any guidance or codes of practice issued by the relevant government department concerning the legislation.

Catastrophic Failure:

(a) a failure by the Provider for whatever reason to implement the Disaster Recovery Plan successfully and in accordance with its terms on the occurrence of a Disaster.

(b) any action by the Provider, whether in relation to the Services and this agreement or otherwise, which in the reasonable opinion of the Authority's Authorised Representative has or may cause significant harm to the reputation of the Authority.

Change: any change to this agreement including to any of the Services.

Change Control Procedure: the procedure for changing this agreement, as set out in 0.

Change in Law: any change in any Applicable Law which impacts on the performance of the Services and which comes into force after the Commencement Date.

Charges: the charges due and payable by the Authority to the Service Provider in respect of the Services in accordance with the provisions of this agreement, such charges are set out in the Service Provider's Tender at Schedule 3.

Commencement Date: the date of this agreement**.**

Commercially Sensitive Information: the information listed in Schedule 9 comprising the information of a commercially sensitive nature relating to the Service Provider, its intellectual property rights or its business or which the Service Provider has indicated to the Authority that, if disclosed by the Authority, would cause the Service Provider significant commercial disadvantage or material financial loss.

Contract Year: a period of 12 months, commencing on the Commencement Date

Daily Rate: the sum of money paid by the Authority to the Service Provider as part of the Charges for each Route as set out in the Service Provider's Tender.

Controller, Processor, Data Subject, Personal Data, Personal Data Breach, Data Protection Officer: have the same meaning as set out in the GDPR.

Data Controller: the entity which alone or jointly with others determines the purposes and the means of the Processing of Personal Data;

Data Protection Legislation: the Data Protection Act 2018 (**DPA**), the General Data Protection Regulation (**GDPR**) (Regulation (EU) 2016/679), the Law Enforcement Directive (LED) (Directive (EU) 2016/680) the Regulation of Investigatory Powers Act 2000, the Telecommunications (Lawful Business Practice) (Interception of Communications) Regulations 2000, the Electronic Communications Data Protection Directive 2002/58/EC, the Privacy and Electronic Communications (EC Directive) Regulations 2003 and all applicable laws and regulations relating to processing of personal data and privacy, including where applicable the guidance and codes of practice issued by the Information Commissioner.

Data Loss Event: any event that results, or may result, in unauthorised access to Personal Data held by the Service Provider under this Agreement, and/or actual or potential loss and/or destruction of Personal Data in breach of this Agreement, including any Personal Data Breach**.**

Data Security and protection Toolkit or DSPT: Online self-assessment tool that enables organisations to measure and publish their performance against the National Data Guardian's ten data security standards.

Data Subject: a natural person whose Personal Data are processed in the context of this Contract.

Data Subject Access Request: a request made by, or on behalf of, a Data Subject in accordance with rights granted pursuant to the Data Protection Legislation to access their Personal Data.

Data Protection Impact Assessment: an assessment by the Service Provider of the impact of the envisaged processing on the protection of Personal Data.

DBS: has the meaning given to it in clause 10.2

DBS Certificate: means a certificate from a DBS check carried out in accordance with clause 10.

DPS: has the meaning given to it in Recital (A)

Default Notice: is defined in clause **Error! Reference source not found.**.

Dispute Resolution Procedure: the procedure set out in clause 14.

Environmental Information Regulations: the Environmental Information Regulations 2004 (SI 2004/3391) together with any guidance and/or codes of practice issued by the Information Commissioner or relevant government department in relation to such regulations.

Extension Period: a period of one year from the end of the Initial Term.

Exit Management Plan: the plan set out in 0.

FOIA: the Freedom of Information Act 2000, and any subordinate legislation made under the Act from time to time, together with any guidance and/or codes of practice issued by the Information Commissioner or relevant government department in relation to such legislation.

Force Majeure: any cause affecting the performance by a party of its obligations under this agreement arising from acts, events, omissions or non-events beyond its reasonable control, including acts of God, riots, war, acts of terrorism, fire, flood, storm or earthquake and any disaster, but excluding any industrial dispute relating to the Service Provider, the Service Provider's Personnel or any other failure in the Service Provider's supply chain.

GDPR: the EU General Data Protection Regulation 2016/679

Health and Safety Policy: the health and safety policy of the Authority [and/or other relevant Central Government Body] as provided to the Provider on or before the Commencement Date and as subsequently provided to the Provider from time to time except any provision of any such subsequently provided policy that cannot be reasonably reconciled to ensuring compliance with applicable Law regarding health and safety.

Information: has the meaning given under section 84 of FOIA.

Initial Term: the period commencing on the Commencement Date and ending on the fourth anniversary of the Commencement Date.

Insolvency Event: where:

(a) the Provider suspends, or threatens to suspend, payment of its debts or is unable to pay its debts as they fall due or admits inability to pay its debts or (being a company or limited liability partnership) is deemed unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986 OR (being an individual) is deemed either unable to pay its debts or as having no reasonable prospect of so doing, in either case, within the meaning of section 268 of the Insolvency Act 1986 OR (being a partnership) has any partner to whom any of the foregoing apply;

(b) the Provider commences negotiations with all or any class of its creditors with a view to rescheduling any of its debts, or makes a proposal for or enters into any compromise or arrangement with its creditors other than (being a company) for the sole purpose of a scheme for a solvent amalgamation of the Provider with one or more other companies or the solvent reconstruction of that other party;

(c) a petition is filed, a notice is given, a resolution is passed, or an order is made, for or in connection with the winding up of that other party (being a company) other than for the sole purpose of a scheme for a solvent amalgamation of that other party with one or more other companies or the solvent reconstruction of that other party;

(d) an application is made to court, or an order is made, for the appointment of an administrator, or if a notice of intention to appoint an administrator is given or if an administrator is appointed, over the Provider (being a company);

(e) the holder of a qualifying floating charge over the assets of the Provider (being a company) has become entitled to appoint or has appointed an administrative receiver; (i) a person becomes entitled to appoint a receiver over the assets of the Provider or a receiver is appointed over the assets of the Provider;

(f) a creditor or encumbrancer of the Provider attaches or takes possession of, or a distress, execution, sequestration or other such process is levied or enforced on or sued

against, the whole or any part of the other party's assets and such attachment or process is not discharged within 14 days;

(g) any event occurs, or proceeding is taken, with respect to the other party in any jurisdiction to which it is subject that has an effect equivalent or similar to any of the events mentioned in (a) to (g) (inclusive); or

(h) the Provider suspends or ceases, or threatens to suspend or cease, carrying on all or a substantial part of its business.

Intellectual Property: any and all intellectual property rights of any nature anywhere in the world whether registered, registerable or otherwise, including patents, utility models, trade marks, registered designs and domain names, applications for any of the foregoing, trade or business names, goodwill, copyright and rights in the nature of copyright, design rights, rights in databases, moral rights, know-how and any other intellectual property rights which subsist in computer software, computer programs, websites, documents, information, techniques, business methods, drawings, logos, instruction manuals, lists and procedures and particulars of customers, marketing methods and procedures and advertising literature, including the "look and feel" of any websites.

KPIs: the key performance indicators set out in Schedule 2.

Key Personnel: those personnel identified 0 for the roles attributed to such personnel, as modified pursuant to clause 12..

Law: any law, statute, subordinate legislation within the meaning of section 21(1) of the Interpretation Act 1978, bye-law, enforceable right within the meaning of section 2 of the European Communities Act 1972, regulation, order, mandatory guidance or code of practice, judgment of a relevant court of law, or directives or requirements of any regulatory body with which the Provider is bound to comply;

Management Reports: the reports to be prepared and presented by the Provider in accordance with schedule 1 to include a comparison of Achieved KPIs with the Target KPIs in the measurement period in question and measures to be taken to remedy any deficiency in Achieved KPIs.

Necessary Consents: all approvals, certificates, authorisations, permissions, licences, permits, regulations and consents necessary from time to time for the performance of the Service.

Payment Plan: the plan for payment of the Charges as set out in Schedule 4.

Personal Data: any information relating to an identified or identifiable natural person including ‘special’ categories of personal data set out in Article 9(1) of the GDPR. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural, or social identity of that natural person.

Prohibited Act: the following constitute Prohibited Acts:

(a) to directly or indirectly offer, promise or give any person working for or engaged by the Authority a financial or other advantage to:

(i) induce that person to perform improperly a relevant function or activity; or

(ii) reward that person for improper performance of a relevant function or activity;

(b) to directly or indirectly request, agree to receive or accept any financial or other advantage as an inducement or a reward for improper performance of a relevant function or activity in connection with this agreement;

(c) committing any offence:

(i) under the Bribery Act;

(ii) under legislation creating offences concerning fraudulent acts;

(iii) at common law concerning fraudulent acts relating to this agreement or any other contract with the Authority; or

(iv) defrauding, attempting to defraud or conspiring to defraud the Authority.

(v) section 117 of the Local Government Act 1972.

Permitted Recipients: the parties to this Contract, the directors, officers, staff and employees of each Party, any third parties engaged to perform obligations in connection with this Contract;

Processing of Personal Data or "Processing/Process": operation or set of operations which is performed on Personal Data or on sets of Personal Data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction;

Project: services to be provided as described in Schedule 1

Protective Measures: appropriate technical and organisational measures which may include: pseudonymising and encrypting Personal Data, ensuring confidentiality integrity availability and resilience of systems and services ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident and regularly assessing and evaluating the effectiveness of such measures adopted by it;

Regulated Activity: in relation to children shall have the same meaning as set out in Part 1 of Schedule 4 to the Safeguarding Vulnerable Groups Act 2006 and in relation to vulnerable adults shall have the same meaning as set out in Part 2 of Schedule 4 to the Safeguarding Vulnerable Groups Act 2006.

Regulated Activity Provider: shall have the same meaning as set out in section 6 of the Safeguarding Vulnerable Groups Act 2006.

Relevant Transfer: a relevant transfer for the purposes of TUPE.

Replacement Services: any services that are identical or substantially similar to any of the Services and which the Authority receives in substitution for any of the Services following the termination or expiry of this agreement, whether those services are provided by the Authority internally or by any Replacement Service Provider.

Replacement Service Provider: means any third party service provider appointed by the Authority to supply any services which are substantially similar to any of the Services and which the Authority receives in substitution for any of the Services following the expiry, termination or partial termination of the Contract.

Request for Information: a request for information or an apparent request under the Code of Practice on Access to Government Information, FOIA or the Environmental Information Regulations.

Returning Employees: means those persons listed in a Schedule to be agreed between the parties prior to the end of the Term who it is agreed were employed by the Service Provider (and/or any sub-contractor) wholly or mainly in the Services immediately before the end of the Term

Service Commencement Date: the commencement date specified as set out in the Specification

Service Levels: the service levels to which the Services are to be provided, as set out in Schedule 2.

Service Provider, Clinical Service Provider: the Service Provider's agents and contractors, including each Sub-Contractor.

Service Provider's Personnel: all employees, staff, other workers, agents and consultants of the Service Provider and of any Sub-Contractors who are engaged in the provision of the Services from time to time.

Service Provider's Tender: the tender submitted by the Service Provider and other associated documentation set out in 0.

Services: the services to be delivered by or on behalf of the Service Provider under this agreement, as more particularly described in the Specification

Specification: the specification at Schedule 1

Sub-Contract: any contract between the Service Provider and a third party pursuant to which the Service Provider agrees to source the provision of any of the Services from that third party.

Sub-Contractor: the contractors or service providers that enter into a Sub-Contract with the Service Provider.

Sub-Processor: any third party appointed to process Personal Data on behalf of the Contractor related to this agreement;

System: Pharmoutcome software as described in Schedule 13

Term: shall have the meaning given in clause 2.1

Termination Date: the date of expiry or termination of this agreement.

Transferring Employees: has the meaning given in clause 11.1

Healthcare Specific Requirements: are set out in Schedule 8

TUPE: the Transfer of Undertakings (Protection of Employment) Regulations 2006 (SI 2006/246) as amended from time to time.

Working Day: Monday to Friday, excluding any public holidays in England and Wales.

1.2 Clause, schedule and paragraph headings shall not affect the interpretation of this agreement.

1.3 A person includes a natural person, corporate or unincorporated body (whether or not having separate legal personality) [and that person's legal and personal representatives, successors and permitted assigns].

1.4 The schedules form part of this agreement and shall have effect as if set out in full in the body of this agreement and any reference to this agreement includes the schedules.

1.5 A reference to a company shall include any company, corporation or other body corporate, wherever and however incorporated or established.

1.6 Words in the singular shall include the plural and vice versa.

1.7 A reference to one gender shall include a reference to the other genders.

1.8 A reference to a statute or statutory provision is a reference to it as it is in force for the time being, taking account of any amendment, extension, or re-enactment and includes any subordinate legislation for the time being in force made under it.

1.9 A reference to writing or written includes faxes and e-mail.

1.10 Any obligation in this agreement on a person not to do something includes an obligation not to agree or allow that thing to be done.

1.11 A reference to a document is a reference to that document as varied or novated (in each case, other than in breach of the provisions of this agreement) at any time.

1.12 References to clauses and schedules are to the clauses and schedules of this agreement; references to paragraphs are to paragraphs of the relevant schedule.

1.13 Where there is any conflict or inconsistency between the provisions of the agreement, such conflict or inconsistency shall be resolved according to the following order of priority:

(a) the clauses of the agreement;

(b) Schedule 1 to this agreement;

(c) the remaining schedules to this agreement other than 0;

(d) 0 to this agreement.

COMMENCEMENT AND DURATION

2. TERM

2.1 This Agreement shall take effect on the Commencement Date and shall continue for the Initial Term unless terminated earlier in accordance with the terms of this agreement.

3. CONSENTS, SERVICE PROVIDER'S WARRANTY AND DUE DILIGENCE

3.1 The Service Provider shall ensure that all Necessary Consents are in place to provide the Services and the Authority shall not (unless otherwise agreed) incur any additional costs associated with obtaining, maintaining or complying with the same.

3.2 Where there is any conflict or inconsistency between the provisions of the agreement and the requirements of a Necessary Consent, then the latter shall prevail, provided that the Service Provider has made all reasonable attempts to obtain a Necessary Consent in line with the requirements of the Services.

3.3 The Service Provider acknowledges and confirms that:

(a) it has had an opportunity to carry out a thorough due diligence exercise in relation to the Services and has asked the Authority all the questions it considers to be relevant for the purpose of establishing whether it is able to provide the Services in accordance with the terms of this agreement;

(b) it has received all information requested by it from the Authority pursuant to clause 3.3(a) to enable it to determine whether it is able to provide the Services in accordance with the terms of this agreement;

(c) it has made and shall make its own enquiries to satisfy itself as to the accuracy and adequacy of any information supplied to it by or on behalf of the Authority pursuant to clause 3.3(b);

(d) it has raised all relevant due diligence questions with the Authority before the Commencement Date; and

(e) it has entered into this agreement in reliance on its own due diligence.

3.4 Save as provided in this agreement, no representations, warranties or conditions are given or assumed by the Authority in respect of any information which is provided to the Service Provider by the Authority and any such representations, warranties or conditions are excluded, save to the extent that such exclusion is prohibited by law.

3.5 The Service Provider:

(a) as at the Commencement Date, warrants and represents that all information contained in the Service Provider's Tender remains true, accurate and not misleading, save as may have been specifically disclosed in writing to the Authority prior to execution of the agreement; and

(b) shall promptly notify the Authority in writing if it becomes aware during the performance of this agreement of any inaccuracies in any information provided to it by the Authority during such due diligence which materially and adversely affects its ability to perform the Services or meet any Service Levels.

3.6 The Service Provider shall not be entitled to recover any additional costs from the Authority which arise from, or be relieved from any of its obligations as a result of, any matters or inaccuracies notified to the Authority by the Service Provider in accordance with clause 3.5(b) save where such additional costs or adverse effect on performance have been caused by the Service Provider having been provided with fundamentally misleading information by or on behalf of the Authority and the Service Provider could not reasonably have known that the information was incorrect or misleading at the time such information was provided. If this exception applies, the Service Provider shall be entitled to recover such reasonable additional costs from the Authority or shall be relieved from performance of certain obligations as shall be determined by the Change Control Procedure.

3.7 Nothing in this clause 3 shall limit or exclude the liability of the Authority for fraud or fraudulent misrepresentation.

4. EXCLUSIVITY

4.1. During the Term of this Agreement neither party nor any of its affiliates shall induce solicit or entice, or endeavour to induce, solicit or entice away from the other party or employ any person who at any time during the Term is employed by the other party or who is a consultant to the other party and with whom the first party has come into contact as a result of this Agreement or this Project. If a party is in breach of this clause 4.1 then, without limiting any other right or remedy which the other party may have pursuant to such breach, the party in breach shall reimburse such other party in respect of all charges, fees, costs and expenses reasonably paid by that party to any recruitment agencies or other third parties in consideration of the provision by such

agency or third party of recruitment services for the purpose of the recruitment of a replacement for the employee so enticed or solicited.

4.2. Nothing in this Agreement shall prevent the Authority from appointing or procuring the provision by a third party of any services the same as or similar to the Services.

THE SERVICES

5. SUPPLY OF SERVICES, SERVICE STANDARDS & SERVICE FAILURE

5.1 The Service Provider shall provide the Services to the Authority with effect from the Service Commencement Date and for the duration of this Agreement in accordance with the provisions of this Agreement.

5.2 In the event that the Provider does not comply with the provisions of clause 5.1 in any way, the Authority may serve the Provider with a notice in writing setting out the details of the Provider's default (a **Default Notice**).

5.3 Without prejudice to clause 5.1, the Service Provider shall provide the Services, or procure that they are provided:

(a) with reasonable skill and care and in accordance with the best practice prevailing in the healthcare industry from time to time;

(b) in all respects in accordance with the provisions of this agreement and the Specification; and

(c) in accordance with all Applicable Laws.

5.4 In providing the Services, the Service Provider shall comply and ensure compliance at all times by the Service Provider's Personnel with the Healthcare Specific Requirements.

5.5 Without limiting the general obligation set out in clause 5.3, the Service Provider shall (and shall procure that the Service Provider's Personnel shall):

(a) at all times comply with the provisions of the Human Rights Act 1998 in the performance of this agreement. The Service Provider shall also undertake, or refrain from undertaking, such acts as the Authority requests so as to enable the Authority to comply with its obligations under the Human Rights Act 1998; and

(b) not unlawfully discriminate within the meaning and scope of any law, enactment, order or regulation relating to discrimination in employment.

5.6 The Service Provider shall provide the Authority with such information in connection with the Services and the provision thereof as the Authority may, from time to time, reasonably require both before and during the provision of the Services.

5.7 For the purpose of the Service, the Service Provider shall use The System as set out in Schedule 13 (Service Level Agreement – License)

5.8 The Service Provider shall perform its obligations under this Agreement in a reasonable and timely manner in accordance with the provisions of this Agreement.

5.9 In the event that the Service Provider fails to comply with the provisions of this clause 5 in any way and without prejudice to any other rights or remedies the Authority may have, the Authority may suspend or terminate this agreement in accordance with the provisions of Schedule 2.

5.10 **INFORMATION GOVERNANCE MANAGEMENT**

5.11 There should be proactive use of information within the Service Provider organisation, both for patient care and service management as determined by law, statute and best practice.

5.12 There should be proactive use of information between the Service Provider, other NHS and partner organisations to support patient care as determined by law, statute and best practice.

5.13 The Service Provider will establish and maintain policies and procedures to ensure compliance with requirements contained in the Data Security and Protection Toolkit.

5.14 The Service Provider will annually assess its performance against the requirements set out in the NHS Data Security and Protection Toolkit. The Service Provider will report the results of its self assessment to the Department of Health in accordance with current guidance in the Data Security and Protection Toolkit.

5.15 The Service Provider will follow a program of continual improvement to increase the Data Security and Protection compliance in the Service Provider organisation year on year.

5.16 Individual members of staff will be provided with the opportunity to attend training and awareness sessions to equip them to meet their individual responsibilities in relation to the Data Security and Protection Toolkit.

5.17 Where appropriate the principles of information management and handling outlined in this policy are to be applied to identifiable information about the Service Provider staff as well as service users.

6. HEALTH AND SAFETY

6.1 The Service Provider shall promptly notify the Authority of any health and safety hazards, which may arise in connection with the performance of the agreement. The Authority shall promptly notify the Service Provider of any health and safety hazards that may exist or arise at the Authority's Premises which may affect the Service Provider in the performance of the agreement.

6.2 While on the Authority's Premises, the Service Provider shall comply with any health and safety measures implemented by the Authority and other persons working on the Authority's Premises.

6.3 The Service Provider shall notify the Authority immediately in the event of any incident occurring in the performance of the agreement on the Authority's Premises where that incident causes any personal injury or damage to property that could give rise to personal injury.

6.4 The Service Provider shall comply with the requirements of the Health and Safety at Work etc. Act 1974 and any other acts, orders, regulations and codes of practice relating to health and safety, which may apply to staff and other persons working on the Authority's Premises in the performance of the agreement.

6.5 The Service Provider shall ensure that its health and safety policy statement (as required by the Health and Safety at Work etc Act 1974) is made available to the Authority on request.

7. AUTHORITY'S PREMISES AND ASSETS

7.1 The Authority shall, subject to clause 6 and clause 10, provide the Service Provider (and its Sub-Contractors) with access to such parts of the Authority's Premises as the Service Provider reasonably requires for the purposes only of properly providing the Services.

7.2 The Authority shall provide the Service Provider with such accommodation and facilities in the Authority's Premises as is specified in Schedule 10 or which is otherwise agreed by the parties from time to time.

7.3 Subject to the requirements of clause 29 and the Exit Management Plan, in the event of the expiry or termination of the agreement, the Authority shall on reasonable notice provide the Service Provider with such access as the Service Provider reasonably requires to the Authority's Premises to remove any of the Service Provider's equipment. All such equipment shall be promptly removed by the Service Provider.

7.4 The Service Provider shall ensure that:

(a) where using the Authority's Premises and any Authority Assets they are kept properly secure and it will comply and cooperate with the Authority's Authorised Representative's reasonable directions regarding the security of the same;

(b) only those of the Service Provider's Personnel that are duly authorised to enter upon the Authority's Premises for the purposes of providing the Services, do so;

(c) any Authority Assets used by the Service Provider are maintained (or restored at the end of the Term) in the same or similar condition as at the Commencement Date (fair wear and tear excepted) and are not removed from Authority Premises unless expressly permitted under this agreement or by the Authority's Authorised Representative.

7.5 The Authority shall maintain and repair the Authority Assets, however, where such maintenance or repair arises directly from the act, omission, default or negligence of the Service Provider or its representatives (fair wear and tear excluded) the costs incurred by the Authority in maintaining and repairing the same shall be recoverable from the Service Provider as a debt.

7.6 The Service Provider shall notify the Authority immediately on becoming aware of any damage caused by the Service Provider, its agents, employees or Sub-Contractors to any property of the Authority, to any of the Authority's Premises or to any property of any other recipient of the Services in the course of providing the Services.

CHARGES AND PAYMENT

8. PAYMENT

8.1 Except as expressly provided for in this agreement, in consideration of the provision of the Services by the Service Provider in accordance with the terms and conditions of this agreement, the Authority shall pay the Charges to the Service Provider.

8.2 The Service Provider shall invoice the Authority for payment of the Charges at the end of each calendar month. All invoices shall be directed to the Authority's Representative.

8.3 The Authority shall consider and verify the invoice in a timely fashion.

8.4 The Authority shall pay the Charges which have become payable within 30 days of verifying the invoice in accordance with clause 8.3. Where the Authority fails to comply with clause 8.3 and there is an undue delay in considering and verifying the invoice the invoice shall be regarded as valid and undisputed for the purposes of this paragraph after a reasonable period has passed.

8.5 Where any party disputes any sum to be paid by it then a payment equal to the sum not in dispute shall be paid and the dispute as to the sum that remains unpaid shall be determined in accordance with clause 16. Provided that the sum has been disputed in good faith, interest due on any sums in dispute shall not accrue until the earlier of 30 calendar days after resolution of the dispute between the parties.

8.6 Subject to clause 8.5, interest shall be payable on the late payment of any undisputed Charges properly invoiced under this agreement in accordance with the Late Payment of Commercial Debts (Interest) Act 1998. The Service Provider shall not suspend the supply of the Services if any payment is overdue.

8.7 The Charges are stated exclusive of VAT, which shall be added at the prevailing rate as applicable and paid by the Authority following delivery of a valid VAT invoice. The Service Provider shall indemnify the Authority against any liability (including any interest, penalties or costs incurred) which is levied, demanded or assessed on the Authority at any time in respect of the Service Provider's failure to account for, or to pay, any VAT relating to payments made to the Service Provider under this agreement.

8.8 The Service Provider shall maintain complete and accurate records of, and supporting documentation for, all amounts which may be chargeable to the Authority pursuant to this agreement. Such records shall be retained for inspection by the Authority for 7 years from the end of the Contract Year to which the records relate.

8.9 Where the Service Provider enters into a Sub-Contract with a supplier or contractor for the purpose of performing the agreement, it shall cause a term to be included in such a Sub-Contract (and any further sub-contracts in its supply chain) that have the same effect as clause 8.3 and 8.4.

8.10 The Authority may retain or set off any sums owed to it by the Service Provider which have fallen due and payable against any sums due to the Service Provider under this agreement or any other agreement pursuant to which the Service Provider or any Associated Company of the Service Provider provides goods or services to the Authority.

8.11 The Service Provider shall make any payments due to the Authority without any deduction whether by way of set-off, counterclaim, discount, abatement or otherwise,

unless the Service Provider has a valid court order requiring an amount equal to such deduction to be paid by the Authority to the Service Provider.

STAFF

9. PERSONNEL USED TO PROVIDE THE SERVICES

9.1 At all times, the Service Provider shall ensure that:

(a) each of the Service Provider's Personnel is suitably qualified, adequately trained and capable of providing the applicable Services in respect of which they are engaged;

(b) there is an adequate number of Service Provider's Personnel to provide the Services properly;

(c) only those people who are authorised by the Service Provider (under the authorisation procedure to be agreed between the parties) are involved in providing the Services; and

(d) NOT USED.

9.2 NOT USED.

9.3 The Service Provider shall replace any of the Service Provider's Personnel who the Authority reasonably decides have failed to carry out their duties with reasonable skill and care. Following the removal of any of the Service Provider's Personnel for any reason, the Service Provider shall ensure such person is replaced promptly with another person with the necessary training and skills to meet the requirements of the Services.

9.4 The Service Provider shall maintain up-to-date personnel records on the Service Provider's Personnel engaged in the provision of the Services and, on request, provide reasonable information to the Authority on the Service Provider's Personnel. The Service Provider shall ensure at all times that it has the right to provide these records in compliance with the applicable Data Protection Legislation.

9.5 The Service Provider shall use its best endeavours to ensure continuity of personnel and to ensure that the turnover rate of its staff engaged in the provision or management of the Services is at least as good at the prevailing industry norm for similar services, locations and environments.

10. SAFEGUARDING CHILDREN AND VULNERABLE ADULTS

10.1 The parties acknowledge that the Service Provider is a Regulated Activity Provider with ultimate responsibility for the management and control of the Regulated Activity provided under this agreement and for the purposes of the Safeguarding Vulnerable Groups Act 2006.

10.2 The Service Provider shall ensure that prior to engaging any individuals in the provision of the Services, all individuals are:

(a) subject to a valid enhanced disclosure check undertaken through the Disclosure and Barring Service ("DBS") including a check against the adults' barred list or the children's barred list, as appropriate; and

(b) the Service Provider shall monitor the level and validity of the checks under this clause 10.2 for each member of staff.

and the DBS certificates resulting from such checks shall be made available for inspection by the Authority on request by the Authority.

10.3 If any individual falling within clause 10.2 has an existing valid enhanced DBS certificate, the Service Provider may accept such a certificate PROVIDED THAT:

(a) The individual's details match those on the DBS certificate;

(b) the disclosure is at the correct level and type for the Services that individual will be engaged in;

(c) the individual has signed up to the DBS update service and the Service Provider has carried out an update check on that individual; and

(d) the Service Provider warrants to the Authority that it has carried out an update check on that individual with the DBS and is satisfied as to its result.

10.4 The Service Provider warrants that at all times for the purposes of this agreement it has no reason to believe that any person who is or will be employed or engaged by the Service Provider in the provision of the Services is barred from the activity in accordance with the provisions of the Safeguarding Vulnerable Groups Act 2006 and any regulations made thereunder, as amended from time to time.

10.5 The Service Provider shall immediately notify the Authority of any information that the Authority reasonably requests to enable it to be satisfied that the obligations of this clause 10 have been met.

10.6 The Service Provider shall refer information about any person carrying out the Services to the DBS where it removes permission for such person to carry out the Services (or would have, if such person had not otherwise ceased to carry out the Services)

because, in its opinion, such person has harmed or poses a risk of harm to any service users including children and vulnerable adults.

10.7 The Service Provider shall not employ or use the services of any person who is barred from, or whose previous conduct or records indicate that they would not be suitable to carry out Regulated Activity or who may otherwise present a risk to service users.

10.8 The Service Provider shall bear the cost of all checks on the Service Provider's Personnel required in accordance with this clause 10.

11. TUPE

11.1 The parties hereby acknowledge that, pursuant to the Transfer of Undertakings (Protection of Employment) Regulations 2006 ("**TUPE**"), there will be a Relevant Transfer on the Commencement Date and the contracts of employment for those employees who are wholly or mainly assigned in the Services immediately before the Commencement Date ("**the Transferring Employees**") will take effect as if originally made between the Service Provider and the employees (save for those who object pursuant to Regulation 4(7) of TUPE).

11.2 The Authority shall indemnify and keep indemnified and hold the Service Provider harmless from and against all actions, suits, claims, demands, losses, charges, damages, costs and expenses and other liabilities which the Service Provider may suffer or incur as a result of or in connection with:

(a) any claim or demand by any Transferring Employee (whether in contract, tort, under statute, pursuant to European Law or otherwise) in each case arising directly or indirectly from any act, fault or omission of the Authority in respect of any Transferring Employee on or before the Commencement Date.

(b) any claim (including any individual employee entitlement under or consequent on such a claim) by any trade union or other body or person representing any Transferring Employees arising from or connected with any failure by the Authority to comply with any legal obligation to such trade union, body or person;

11.2 The Service Provider shall be responsible for all emoluments and outgoings in respect of the Transferring Employees (including, without limitation, all wages, bonuses, holiday pay, commission, premiums, subscriptions, PAYE and national insurance contributions and pension contributions) which are attributable in whole or in part to the period on or after the Commencement Date (including any bonuses, holiday pay, commission, premiums, subscriptions and any other prepayments which are payable before the Commencement Date but which are attributable in whole or in part to the period on or after the Commencement Date and will indemnify and keep indemnified and hold the

Authority harmless from and against all actions, suits, claims, damages, costs and expenses and other liabilities which the Authority may incur as a result of the same.

11.3 Not later than twelve months prior to the end of the Term, the Service Provider shall fully and accurately disclose to the Authority all information that the Authority may reasonably request in relation to the Service Provider's Personnel including the following:

(a) the total number of Service Provider's Personnel whose employment/engagement shall terminate at the end of the Term, save for any operation of law; and

(b) the age, gender, salary or other remuneration, future pay settlements and redundancy and pensions entitlements of the Service Provider's Personnel referred to in clause 11.3(a); and

(c) the terms and conditions of employment/engagement of the Service Provider's Personnel referred to in clause 11.3(a), their job titles and qualifications; and

(d) details of any current disciplinary or grievance proceedings ongoing or circumstances likely to give rise to such proceedings and details of any claims current or threatened; and

(e) details of all collective agreements with a brief summary of the current state of negotiations with such bodies and with details of any current industrial disputes and claims for recognition by any trade union.

11.4 At intervals to be stipulated by the Authority (which shall not be more frequent than every thirty days) and immediately prior to the end of the Term the Service Provider shall deliver to the Authority a complete update of all such information which shall be disclosable pursuant to clause 11.3.

11.5 At the time of providing the information disclosed pursuant to clauses 11.3 and 11.4, the Service Provider shall warrant the completeness and accuracy of all such information and the Authority may assign the benefit of this warranty to any Replacement Service Provider.

11.6 The Authority may use the information it receives from the Authority pursuant to clause 11.3 and 11.4 for the purposes of TUPE and/or any retendering process in order to ensure an effective handover of all work in progress at the end of the Term. The Authority shall provide the Replacement Service Provider with such assistance as it shall reasonably request.

11.7 The Service Provider shall indemnify and keep indemnified and hold the Authority (both for themselves and any Replacement Service Provider) harmless from and against all actions, suits, claims, demands, losses, charges, damages, costs and

expenses and other liabilities which the Authority or any Replacement Service Provider may suffer or incur as a result of or in connection with:

(a) the provision of information pursuant to clause 11; and

(b) any claim or demand by any Returning Employee (whether in contract, tort, under statute, pursuant to European Law or otherwise) in each case arising directly or indirectly from any act, fault or omission of the Service Provider or any sub-contractor in respect of any Returning Employee on or before the end of the Term; and

(c) any failure by the Service Provider or any sub-contractor to comply with its obligations under Regulation 13 or 14 of TUPE or any award of compensation under Regulation 15 of TUPE save where such failure arises from the failure of the Authority or a Replacement Service Provider to comply with its duties under Regulation 13 of the Regulations; and

(d) any claim (including any individual employee entitlement under or consequent on such a claim) by any trade union or other body or person representing any Returning Employees arising from or connected with any failure by the Service Provider or any sub-contractor to comply with any legal obligation to such trade union, body or person; and

(e) any claim by any person who is transferred by the Service Provider to the Authority and/or a Replacement Service Provider whose name is not included in the list of Returning Employees.

11.8 If the Service Provider becomes aware that the information it provided pursuant to clause 11.4 has become untrue, inaccurate or misleading, it shall notify the Authority and provide the Authority with up to date information.

11.9 This clause applies during the Term and indefinitely thereafter.

11.10 The Service Provider undertakes to the Authority that, during the twelve months prior to the end of the Term the Service Provider shall not (and shall procure that any sub-contractor shall not) without the prior consent of the Authority (such consent not to be unreasonably withheld or delayed):

(a) amend or vary (or purport or promise to amend or vary) the terms and conditions of employment or engagement) (including, for the avoidance of doubt, pay) of any Service Provider's Personnel (other than where such amendment or variation has previously been agreed between the Service Provider and the Service Provider's Personnel in the normal course of business, and where any such amendment or variation is not in any way related to the transfer of the Services);

(b) terminate or give notice to terminate the employment or engagement of any Service Provider's Personnel (other than in circumstances in which the termination is for reasons of misconduct or lack of capability);

(c) transfer away, remove, reduce or vary the involvement of any of the Service Provider's Personnel from or in the provision of the Services (other than where such transfer or removal:

(i) was planned as part of the individual's career development;

(ii) takes place in the normal course of business; and

(iii) will not have any adverse impact upon the delivery of the Services by the Service Provider, (PROVIDED THAT any such transfer, removal, reduction or variation is not in any way related to the transfer of the Services));

(d) recruit or bring in any new or additional individuals to provide the Services who were not already involved in providing the Services prior to the relevant period.

CONTRACT MANAGEMENT

12. MONITORING

12.1 The Authority may monitor the performance of the Services by the Service Provider.

12.2 The Service Provider shall co-operate, and shall procure that its Sub-Contractors co-operate, with the Authority in carrying out the monitoring referred to in clause 12.1 at no additional charge to the Authority.

12.3 The Service Provider shall monitor its own performance of the Services.

13. CHANGE IN LAW, CHANGE CONTROL AND CONTINUOUS IMPROVEMENT

Change in Law

13.1 The Service Provider shall neither be relieved of its obligations to supply the Services in accordance with the terms of this agreement nor be entitled to an increase in the Charges as the result of any Change in Law

Change Control

13.2 Where a Change is requested by the Authority, the Service Provider shall use reasonable endeavours to agree a fair adjustment to the Charges.

13.3 Where agreement cannot be reached within 14 Working Days either the Authority or the Service Provider shall be entitled to terminate this Agreement in accordance with the provision in clause 25.

13.4 For the avoidance of doubt, the Service Provider is considered to have taken into account all reasonable circumstances in preparing its tender and no Change to the agreement or the Charges will be considered to accommodate the failure of the Service Provider to make adequate provision, financial or otherwise, for the performance of the agreement wholly in accordance with the Specification and in the event that the Service Provider has failed to make such adequate provision, the Authority shall be entitled to terminate this contract in accordance with the provisions of clause 25 and 26 PROVIDED THAT if the Service Provider becomes aware of any problem in operation or any change in the Specification which it has not been notified of by the Authority, the Service Provider must immediately bring this to the attention of the Authority and where it is agreed by the Authority that a Change is required to rectify an unforeseen situation, the Charges may be revised in accordance with Change Control Procedure.

Continuous Improvement

13.5 The Service Provider shall have an ongoing obligation throughout the Term to identify new or potential improvements to the Services. As part of this obligation the Service Provider shall identify and report to the Authority's Representative quarterly in the first Contract Year and once every six months for the remainder of the Term on:

(a) the emergence of new and evolving relevant technologies which could improve the Services;

(b) new or potential improvements to the Services including the quality, responsiveness, performance mechanisms and customer support services in relation to the Services;

(c) new or potential improvements to the interfaces or integration of the Services with other services provided by third parties or the Authority which might result in efficiency or productivity gains or in reduction of operational risk; and

(d) changes in ways of working that would enable the Services to be delivered at lower costs and/or at greater benefits to the Authority.

13.6 Any potential Changes highlighted as a result of the Service Provider's reporting in accordance with clause 13.5 shall be addressed by the parties using the Change Control Procedure.

14. DISPUTE RESOLUTION

14.1 NOT USED.

14.2 Subject to clause 14.1, either party may call an extraordinary meeting of the parties by service of not less than 10 working days written notice and each party agrees to procure that its Authorised Representative together with any other member of Service

Provider's Personnel requested to attend by the Authority (if any) shall attend all extraordinary meetings called in accordance with this clause.

14.3 The members of the relevant meeting shall use their best endeavours to resolve disputes arising out of this agreement. If any dispute referred to a meeting is not resolved at that meeting then either party, by notice in writing to the other, may refer the dispute to **[senior officers of the two parties]** who shall co-operate in good faith to resolve the dispute as amicably as possible within 14 days of service of such notice. If the **[senior officers]** fail to resolve the dispute in the allotted time, then the Dispute Resolution Procedure shall be deemed exhausted.

15. SUB-CONTRACTING AND ASSIGNMENT

15.1 Subject to clause 15.3, neither party shall be entitled to assign, novate or otherwise dispose of any or all of its rights and obligations under this agreement without the prior written consent of the other party, neither may the Service Provider sub-contract the whole or any part of its obligations under this agreement except with the express prior written consent of the Authority.

15.2 In the event that the Service Provider enters into any Sub-Contract in connection with this agreement it shall:

(a) remain responsible to the Authority for the performance of its obligations under the agreement notwithstanding the appointment of any Sub-Contractor and be responsible for the acts omissions and neglects of its Sub-Contractors;

(b) impose obligations on its Sub-Contractor in the same terms as those imposed on it pursuant to this agreement and shall procure that the Sub-Contractor complies with such terms; and

(c) provide a copy, at no charge to the Authority, of any such Sub-Contract on receipt of a request for such by the Authority's Authorised Representative.

15.3 The Authority shall be entitled to novate the agreement to any other body which substantially performs any of the functions that previously had been performed by the Authority.

LIABILITY

16. INDEMNITIES

The Service Provider shall indemnify and keep indemnified the Authority against all actions, proceedings, costs, claims, demands, liabilities, losses and expenses whatsoever whether arising in tort (including negligence) default or breach of this agreement, to the extent that any such loss or claim is due to the breach of contract, negligence, wilful default or fraud of

itself or of its employees or of any of its representatives or sub-contractors save to the extent that the same is directly caused by or directly arises from the negligence, breach of this agreement or applicable law by the Authority or its representatives (excluding any Service Provider's Personnel).

17. LIMITATION OF LIABILITY

17.1 Subject to clause 17.6, neither party shall be liable to the other party (as far as permitted by law) for indirect special or consequential loss or damage in connection with the agreement which shall include, without limitation, any loss of or damage to profit, revenue, contracts, anticipated savings, goodwill or business opportunities whether direct or indirect.

17.2 Not used.

17.3 Each party shall at all times take all reasonable steps to minimise and mitigate any loss or damage for which the relevant party is entitled to bring a claim against the other party pursuant to this agreement.

17.4 Subject to clause 17.6 indemnities given by the Authority in clause 13 is unlimited; and

(a) in respect of all other claims, losses or damages, whether arising from breach of contract or otherwise under or in connection with this agreement (other than a failure to pay any of the Charges that are properly due and payable and for which the Authority shall remain fully liable) is limited to the value of this agreement in the first contract year.

17.5 Subject to clause 17.6, the Service Provider's total aggregate liability:

in respect of the indemnities given by the Service Provider in clauses 13, 18, and 23.2 is unlimited; and

17.6 Notwithstanding any other provision of this agreement neither party limits or excludes its liability for:

(a) fraud or fraudulent misrepresentation;

(b) death or personal injury caused by its negligence;

(c) breach of any obligation as to title implied by statute; or

(d) any other act or omission, liability for which may not be limited under any applicable law.

18. INSURANCE

18.1 The Service Provider shall at its own cost effect and maintain with a reputable insurance company a policy or policies of insurance providing as a minimum the following levels of cover:

(a) public liability insurance with a limit of indemnity of not less than £5,000,000 (five million pounds) in relation to any one claim or series of claims;

(b) employer's liability insurance with a limit of indemnity of not less than £5,000,000 (five million pounds) OR in accordance with any legal requirement for the time being in force in relation to any one claim or series of claims;

(c) insurance in accordance with clause 18.2

(the "**Required Insurances"**) The cover shall be-in respect of all risks which may be incurred by the Service Provider, arising out of the Service Provider's performance of the agreement, including death or personal injury, loss of or damage to property or any other loss. Such policies shall include cover in respect of any financial loss arising from any advice given or omitted to be given by the Service Provider.

18.2 The Service Provider shall give the Authority, on request, copies of all insurance policies referred to in this clause or a broker's verification of insurance to demonstrate that the Required Insurances are in place, together with receipts or other evidence of payment of the latest premiums due under those policies.

18.3 If, for whatever reason, the Service Provider fails to give effect to and maintain the insurances referred to in this clause 18, the Authority may make alternative arrangements to protect its interests and may recover the costs of such arrangements from the Service Provider.

18.4 The terms of any insurance or the amount of cover shall not relieve the Service Provider of any liabilities under the agreement.

18.5 The Service Provider shall hold and maintain the Required Insurances for a minimum of six years following the expiration or earlier termination of the agreement**.**

INFORMATION

19. FREEDOM OF INFORMATION

19.1 The Service Provider acknowledges that the Authority is subject to the requirements of the FOIA and the Environmental Information Regulations and shall assist and co-operate with the Authority (at the Service Provider's expense) to enable the Authority to comply with these information disclosure requirements.

19.2 The Service Provider shall and shall procure that its Sub-Contractors shall:

(a) transfer the Request for Information to the Authority as soon as practicable after receipt and in any event within two Working Days of receiving a Request for Information;

(b) provide the Authority with a copy of all Information in its possession or power in the form that the Authority requires within five Working Days (or such other period as the Authority may specify) of the Authority requesting that Information; and

(c) provide all necessary assistance as reasonably requested by the Authority to enable the Authority to respond to a Request for Information within the time for compliance set out in section 10 of the FOIA or regulation 5 of the Environmental Information Regulations.

19.3 The Authority shall be responsible for determining at its absolute discretion whether the Commercially Sensitive Information and/or any other Information:

(a) is exempt from disclosure in accordance with the provisions of the FOIA or the Environmental Information Regulations; and/or

(b) is to be disclosed in response to a Request for Information.

19.4 In no event shall the Service Provider respond directly to a Request for Information unless expressly authorised to do so by the Authority.

19.5 The Service Provider acknowledges that the Authority may, acting in accordance with the Secretary of State for Constitutional Affairs' Code of Practice on the discharge of public authorities' functions under Part 1 of FOIA (issued under section 45 of the FOIA, November 2004), be obliged under the FOIA or the Environmental Information Regulations to disclose Information:

(a) without consulting with the Service Provider; or

(b) following consultation with the Service Provider and having taken its views into account,

provided always that where clause 19.5(b) applies the Authority shall, in accordance with any recommendations of the Code, take reasonable steps, where appropriate, to give the Service Provider advanced notice, or failing that, to draw the disclosure to the Service Provider's attention after any such disclosure.

19.6 The Service Provider shall ensure that all Information produced in the course of the agreement or relating to the agreement is retained for disclosure and shall permit the Authority to inspect such records as requested from time to time.

19.7 The Service Provider acknowledges that any lists or Schedules provided by it outlining Confidential Information are of indicative value only and that the Authority may nevertheless be obliged to disclose Confidential Information in accordance with clause 19.5.

20. DATA PROTECTION

20.1 The parties agree that in relation to:

(a) Personal Data processed by the Service Provider in providing Services under this Agreement (for example, patient details, medical history and treatment details), the Service Provider shall be the sole Data Controller; and

(b) Personal Data, the processing of which is required by the Authority for the purposes of quality assurance, performance management and contract management the Authority and the Service Provider will be independent Data Controllers;

together the "Agreed Purpose".

20.2 Where the Authority requires information, the Service Provider shall consider whether the requirement can be met by providing anonymised or aggregated data which does not contain Personal Data. Where Personal Data must be shared in order to meet the requirements of the Authority, the Service Provider shall provide such information in pseudonymised form where possible.

20.3 Schedule 12 sets out the categories of Data Subjects, types of Personal Data, Processing operations (including scope, nature and purpose of Processing) and the duration of Processing.

20.4 Each party shall comply with all the obligations imposed on a Data Controller under the Data Protection Laws in relation to all Personal Data that is processed by it in the course of performing its obligations under this Agreement.

20.5 Any material breach of the Data Protection Laws by one party shall, if not remedied within fourteen (14) days of written notice from the other Party, gives grounds to the other Party to terminate this Agreement with immediate effect.

20.6 In relation to the Processing of any Personal Data, each party shall:

(a) ensure that it has all necessary notices and consents in place to enable lawful sharing of Personal Data to the Permitted Recipients for the Agreed Purpose;

(b) give full information to any Data Subject whose Personal Data may be processed under this Agreement of the nature of such Processing;

(c) process the Personal Data only for the Agreed Purpose;

(d) not disclose or allow access to the Personal Data to anyone other than the Permitted Recipients;

(e) ensure that all Permitted Recipients are reliable and have had sufficient training pertinent to the care and handling of Personal Data;

(f) ensure that all Permitted Recipients are subject to written contractual obligations concerning the Personal Data (including obligations of confidentiality) which are no less onerous than those imposed by this Agreement;

(g) ensure that it has in place appropriate technical and organisational measures, to protect against unauthorised or unlawful Processing of Personal Data and against accidental loss or destruction of, or damage to, Personal Data in accordance with Article 32 GDPR;

(h) not transfer any Personal Data outside the European Economic Area unless the transferor ensures that (i) the transfer is to a country approved by the European Commission as providing adequate protection pursuant to Article 45 GDPR; (ii) there are appropriate safeguards in place pursuant to Article 46 GDPR; or (iii) one of the derogations for specific situations in Article 49 GDPR applies to the transfer; and

(i) assist the other party (at its own cost) in responding to any request from a Data Subject and in ensuring its compliance with all applicable requirements and obligations under the Data Protection Laws with respect to security, breach notifications, impact assessments and consultations with supervisory authorities or the UK's Information Authority's Office.

20.7 Each party shall notify the other party without undue delay on becoming aware of any Personal Data Breach under this Agreement.

21. CONFIDENTIALITY

21.1 Subject to clause 21.2, the parties shall keep confidential all matters relating to this agreement and shall use all reasonable endeavours to prevent their representatives from making any disclosure to any person of any matters relating hereto.

21.2 Clause 21.1 shall not apply to any disclosure of information:

(a) required by any applicable law, provided that clause 19.1 shall apply to any disclosures required under the FOIA or the Environment Information Regulations;

(b) that is reasonably required by persons engaged by a party in the performance of such party's obligations under this agreement;

(c) where a party can demonstrate that such information is already generally available and in the public domain otherwise than as a result of a breach of clause 21.1;

(d) by the Authority of any document to which it is a party and which the parties to this agreement have agreed contains no commercially sensitive information;

(e) to enable a determination to be made under clause 14;

(f) which is already lawfully in the possession of the receiving party, prior to its disclosure by the disclosing party;

(g) by the Authority to any other department, office or agency of the Government; and

(h) by the Authority relating to this agreement and in respect of which the Service Provider has given its prior written consent to disclosure.

21.3 On or before the Termination Date the Service Provider shall ensure that all documents and/or computer records in its possession, custody or control which relate to personal information of the Authorities' employees, or service users, are delivered up to the Authority or securely destroyed.

22. AUDIT

22.1 During the Term and for a period of seven years after the Termination Date, the Authority may conduct or be subject to an audit for the following purposes:

(a) to verify the accuracy of Charges (and proposed or actual variations to them in accordance with this agreement) and/or the costs of all suppliers (including Sub-Contractors) of the Services;

(b) to review the integrity, confidentiality and security of any data relating to the Authority or any service users;

(c) to review the Service Provider's compliance with Data Protection Legislation, the FOIA, in accordance with clause 20 (Data Protection) and clause 19 (Freedom of Information) and any other legislation applicable to the Services;

(d) to review any records created during the provision of the Services;

(e) to review any books of account kept by the Service Provider in connection with the provision of the Services;

(f) to carry out the audit and certification of the Authority's accounts;

(g) to carry out an examination pursuant to section 6(1) of the National Audit Act 1983 (or any legislation which may from time to time replace the same) of the economy, efficiency and effectiveness with which the Authority has used its resources;

(h) to verify the accuracy and completeness of the Management Reports delivered or required by this agreement.

22.2 Except where an audit is imposed on the Authority by a regulatory body, the Authority may not conduct an audit under this clause 22 more than twice in any calendar year.

22.3 The Authority shall use its reasonable endeavours to ensure that the conduct of each audit does not unreasonably disrupt the Service Provider or delay the provision of the Services.

22.4 Subject to the Authority's obligations of confidentiality, the Service Provider shall on demand provide the Authority and any relevant regulatory body (and/or their agents or representatives) with all reasonable co-operation and assistance in relation to each audit, including:

(a) all information requested by the above persons within the permitted scope of the audit;

(b) reasonable access to any sites controlled by the Service Provider and to any equipment used (whether exclusively or non-exclusively) in the performance of the Services; and

(c) access to the Service Provider's Personnel.

22.5 The Authority shall endeavour to (but is not obliged to) provide at least 15 days notice of its or, where possible, a regulatory body's, intention to conduct an audit.

22.6 The parties agree that they shall bear their own respective costs and expenses incurred in respect of compliance with their obligations under this clause, unless the audit identifies a material failure to perform its obligations under this agreement in any material manner by the Service Provider in which case the Service Provider shall reimburse the Authority for all the Authority's reasonable costs incurred in the course of the audit.

22.7 If an audit identifies that:

(a) the Service Provider has failed to perform its obligations under this agreement in any material manner, the parties shall agree and implement a remedial plan. If the Service Provider's failure relates to a failure to provide any information to the Authority about the Charges, proposed Charges or the Service Provider's costs, then the remedial plan shall include a requirement for the provision of all such information;

(b) the Authority has overpaid any Charges, the Service Provider shall pay to the Authority the amount overpaid within 20 days. The Authority may deduct the relevant amount from the Charges if the Service Provider fails to make this payment; and

(c) the Authority has underpaid any Charges, the Authority shall pay to the Service Provider the amount of the under-payment [less the cost of audit incurred by the Authority if this was due to a default by the Service Provider in relation to invoicing] within 20 days.

23. INTELLECTUAL PROPERTY

23.1 In the absence of prior written agreement by the Authority to the contrary, all Intellectual Property created by the Service Provider or any employee, agent or subcontractor of the Service Provider:

(a) in the course of performing the Services; or

(b) exclusively for the purpose of performing the Services,

shall vest in the Authority on creation.

23.2 The Service Provider shall indemnify the Authority against all claims, demands, actions, costs, expenses (including legal costs and disbursements on a solicitor and client basis), losses and damages arising from or incurred by reason of any infringement or alleged infringement (including the defence of such alleged infringement) of any Intellectual Property Right by the availability of the Services, except to the extent that they have been caused by or contributed to by the Authority's acts or omissions.

24. SUSPENSION FOR BREACH

24.1 In the event of serious and/or persistent failures to meet the requirements set out in the Specification or any other breach of this agreement, the Authority's Authorised Representative may suspend with immediate effect the whole or any part of the Services in accordance with the procedure set out in Schedule 2 PROVIDED THAT such suspension may not last for longer than six calendar months. During any such suspension, the Service Provider shall not operate the whole or any part of the

Services (as the context requires) and shall not be entitled to any payment of the Charges or compensation from the Authority whether or not the agreement is reinstated following the period of suspension.

TERMINATION

25. TERMINATION FOR BREACH

25.1 The Authority may terminate this agreement in whole or part with immediate effect by the service of written notice on the Service Provider in the following circumstances:

(a) in accordance with the provisions of Schedule 2 (Service Performance Monitoring)

(b) if a resolution is passed or an order is made for the winding up of the Service Provider (otherwise than for the purpose of solvent amalgamation or reconstruction) or the Service Provider becomes subject to an administration order or a receiver or administrative receiver is appointed over or an encumbrancer takes possession of any of the Service Provider's property or equipment;

(c) if the Service Provider ceases or threatens to cease to carry on business in the United Kingdom;

(d) if there is a change of control (as defined in section 574 of the Capital Allowances Act 2001) of the Service Provider to which the Authority reasonably objects.;

(e) if this agreement has been substantially varied other than as permitted under regulation 72 of PCR 2015

(f) if the Service Provider should have been excluded from the procurement process under regulation 57 of PCR 2015;

(g) if the contract should not have been awarded because the Service Provider is in serious breach of its obligations under the Treaty on the Functioning of the European Union ("**TFEU**"), the Treaty on European Union or Directive 2014/24, as declared by the Court of Justice of the European Union in a procedure under Article 258 of the TFEU

25.2 The Authority may terminate this agreement in accordance with the provisions of clause 25. If this agreement is terminated by the Authority for cause such termination shall be at no loss or cost to the Authority and the Service Provider hereby indemnifies the Authority against any such losses or costs which the Authority may suffer as a result of any such termination for cause.

26. TERMINATION ON NOTICE

Either Party may terminate this agreement at any time by giving forty two (42) calendar days' written notice to the other Party.

27. FORCE MAJEURE

27.1 Subject to the remaining provisions of this clause 27, neither party to this agreement shall be liable to the other for any delay or non-performance of its obligations under this agreement to the extent that such non-performance is due to a Force Majeure Event.

27.2 In the event that either party is delayed or prevented from performing its obligations under this agreement by a Force Majeure Event, such party shall:

(a) give notice in writing of such delay or prevention to the other party as soon as reasonably possible, stating the commencement date and extent of such delay or prevention, the cause thereof and its estimated duration;

(b) use all reasonable endeavours to mitigate the effects of such delay or prevention on the performance of its obligations under this agreement; and

(c) resume performance of its obligations as soon as reasonably possible after the removal of the cause of the delay or prevention.

27.3 A party cannot claim relief if the Force Majeure Event is attributable to that party's wilful act, neglect or failure to take reasonable precautions against the relevant Force Majeure Event.

27.4 The Service Provider cannot claim relief if the Force Majeure Event is one where a reasonable service provider should have foreseen and provided for the cause in question.

27.5 As soon as practicable following the affected party's notification, the parties shall consult with each other in good faith and use all reasonable endeavours to agree appropriate terms to mitigate the effects of the Force Majeure Event and to facilitate the continued performance of this agreement. Where the Service Provider is the affected party, it shall take and/or procure the taking of all steps to overcome or minimise the consequences of the Force Majeure Event in accordance with Best Industry Practice.

27.6 The affected party shall notify the other party as soon as practicable after the Force Majeure Event ceases or no longer causes the affected party to be unable to comply with its obligations under this agreement. Following such notification, this agreement shall continue to be performed on the terms existing immediately before the occurrence of the Force Majeure Event unless agreed otherwise by the parties.

27.7 The Authority may, during the continuance of any Force Majeure Event, terminate this agreement by written notice to the Service Provider if a Force Majeure Event occurs that

affects all or a substantial part of the Services and which continues for more than 10 Working Days.

28. PREVENTION OF BRIBERY

28.1 The Service Provider:

(a) shall not, and shall procure that any Service Provider Party and all Service Provider Personnel shall not, in connection with this agreement commit a Prohibited Act;

(b) warrants, represents and undertakes that it is not aware of any financial or other advantage being given to any person working for or engaged by the Authority, or that an agreement has been reached to that effect, in connection with the execution of this agreement, excluding any arrangement of which full details have been disclosed in writing to the Authority before execution of this agreement.

28.2 The Service Provider shall:

(a) if requested, provide the Authority with any reasonable assistance, at the Authority's reasonable cost, to enable the Authority to perform any activity required by any relevant government or agency in any relevant jurisdiction for the purpose of compliance with the Bribery Act;

(b) within 5 Working Days of the Commencement Date, and annually thereafter, certify to the Authority in writing (such certification to be signed by an officer of the Service Provider) compliance with this clause 28 by the Service Provider and all persons associated with it or other persons who are supplying goods or services in connection with this agreement. The Service Provider shall provide such supporting evidence of compliance as the Authority may reasonably request.

28.3 The Service Provider shall have an anti-bribery policy (which shall be disclosed to the Authority) to prevent any Service Provider Party or Service Provider Personnel from committing a Prohibited Act and shall enforce it where appropriate.

28.4 If any breach of clause 28.1 is suspected or known, the Service Provider must notify the Authority immediately.

28.5 If the Service Provider notifies the Authority that it suspects or knows that there may be a breach of clause 28.1, the Service Provider must respond promptly to the Authority's enquiries, co-operate with any investigation, and allow the Authority to audit books, records and any other relevant documentation. This obligation shall continue for seven years following the expiry or termination of this agreement.

28.6 The Authority may terminate this agreement by written notice with immediate effect if the Service Provider, Service Provider Party or Service Provider Personnel (in all cases whether or not acting with the Service Provider's knowledge) breaches clause 28.1

28.7 Any notice of termination under clause 28.6 must specify:

(a) the nature of the Prohibited Act;

(b) the identity of the party whom the Authority believes has committed the Prohibited Act; and

(c) the date on which this agreement will terminate.

28.8 Despite clause 14 (Dispute resolution), any dispute relating to:

(a) the interpretation of clause 28; or

(b) the amount or value of any gift, consideration or commission,

shall be determined by the Authority and its decision shall be final and conclusive.

28.9 Any termination under clause 28.6 will be without prejudice to any right or remedy which has already accrued or subsequently accrues to the Authority.

29. CONSEQUENCES OF TERMINATION

29.1 On the expiry of the Term or if this agreement is terminated in whole or in part for any reason the provisions of the Exit Management Plan shall come into effect and the Service Provider shall co-operate fully with the Authority to ensure an orderly migration of the Services to the Authority or, at the Authority's request, a Replacement Service Provider.

29.2 Without prejudice to any other rights which have accrued or shall accrue to the Authority, on termination by the Authority for a breach of this agreement by the Service Provider in accordance with clause 29, the Authority may at its discretion remove the Service Provider from the DPS in order to ensure the Service.

29.3 On termination of this agreement and on satisfactory completion of the Exit Management Plan (or where reasonably so required by the Authority before such completion) the Service Provider shall procure that all data and other material belonging to the Authority (and all media of any nature containing information and data belonging to the Authority or relating to the Services), shall be delivered to the Authority forthwith and the Service Provider's Authorised Representative shall certify full compliance with this clause.

29.4 The provisions of clause 16 (Indemnities), clause 18 (Insurance), clause 19 (Freedom of Information), clause 20 (Data Protection), clause 22 (Audit), clause 25 (Termination for Breach) and this clause 29 (Consequences of termination) shall survive termination or expiry of this agreement.

GENERAL PROVISIONS

30. WAIVER

No forbearance or delay by either party in enforcing its respective rights will prejudice or restrict the rights of that party, and no waiver of any such rights or of any breach of any contractual terms will be deemed to be a waiver of any other right or of any later breach. In particular, but without limitation to the generality of the foregoing, any prior acceptance or approval communicated by the Authority to the Service Provider in respect of the Services or any omission on the part of the Authority to communicate such prior acceptance or approval shall not relieve the Service Provider of its obligations to deliver the Services in accordance with the provisions of this agreement.

31. CUMULATION OF REMEDIES

Subject to the specific limitations set out in this agreement, no remedy conferred by any provision of this agreement is intended to be exclusive of any other remedy except as expressly provided for in this agreement and each and every remedy shall be cumulative and shall be in addition to every other remedy given thereunder or existing at law or in equity by statute or otherwise.

32. SEVERABILITY

If any of the provisions of this agreement is judged to be illegal or unenforceable, the continuation in full force and effect of the remainder of them will not be prejudiced.

33. PARTNERSHIP OR AGENCY

Nothing in this agreement shall be construed as constituting a partnership between the parties or as constituting either party as the agent of the other for any purpose whatsoever except as specified by the terms of this agreement.

34. THIRD PARTY RIGHTS

34.1 No term of this agreement is intended to confer a benefit on, or to be enforceable by, any person who is not a party to this agreement.

35. PUBLICITY

The Service Provider shall not:

(a) make any press announcements or publicise this agreement or its contents in any way; or

(b) use the Authority's name or brand in any promotion or marketing or announcement of orders,

without the prior written consent of the Authority, [which shall not be unreasonably withheld or delayed].

36. NOTICES

Notices shall be in writing, and shall be sent to the other party marked for the attention of the person at the address set out for such party in this agreement. Notices may be sent by first-class mail or e-mail provided that e-mails are confirmed within 24 hours by first-class mailed confirmation of a copy. Correctly addressed notices sent by first-class mail shall be deemed to have been delivered 72 hours after posting and correctly directed e-mail shall be deemed to have been received instantaneously on transmission provided that they are confirmed as set out above.

37. ENTIRE AGREEMENT

This agreement, the schedules and the documents annexed to it or otherwise referred to in it including the Service Provider's Tender contain the whole agreement between the parties relating to the subject matter hereof and supersede all prior agreements, arrangements and understandings between the parties relating to that subject matter.

38. GOVERNING LAW AND JURISDICTION

38.1 This agreement and any dispute or claim arising out of or in connection with it or its subject matter shall be governed by and construed in accordance with the law of England and Wales.

38.2 The parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this agreement or its subject matter.

This agreement has been entered into on the date stated at the beginning of it.

Signed on behalf of Cambridgeshire County Council::	..... Authorised Signatory

Signed by [NAME OF DIRECTOR] for and on behalf of [NAME OF SERVICE PROVIDER]	..... Director

Schedule 1 **Specifications**

Lot 1: Public Health Community Pharmacy Contract Chlamydia Screening and Treatment

Service Specification: COMMUNITY PHARMACY CHLAMYDIA SCREENING AND TREATMENT, CONDOM DISTRIBUTION SERVICE 2019-20

1. SERVICE DESCRIPTION

1.1 Pharmacies will provide Chlamydia screening postal test kits to asymptomatic sexually active males and females under the age of 25, for example when purchasing condoms, dispensing oral contraceptive pills and supplying EHC.

1.2 When giving out the kit, pharmacy staff will give advice to the young person on how to utilise the kit, how to return it for testing and what will happen following completion of the test.

1.3 The Cambridgeshire Chlamydia Screening Programme will inform people of their results, the options for accessing treatment and will undertake contact tracing and partner notification.

1.4 Pharmacies will act as pick up points for C Card clients and will signpost clients to C Card registration sites.

1.5 Pharmacies will offer a user-friendly, non-judgmental, client-centred and confidential service.

1.6 Pharmacies will refer young people who report symptoms to seek a full sexual health screen at local GUM services and will link into existing local networks of sexual health and community contraceptive services so that there is a robust and rapid referral pathway for people who need onward signposting to services that provide on-going contraception and diagnosis and management of sexually transmitted infections (STIs).

1.7 Pharmacies will provide support and advice to people accessing the service, including advice on safe sex, condom use and advice on the use of regular contraceptive methods, when required.

1.8 Pharmacies may provide treatment to men and women with laboratory confirmed asymptomatic Chlamydia and their partners in line with the Cambridgeshire and Peterborough Patient Group Direction (PGD) for Chlamydia treatment 2018-2021.

2. AIMS AND INTENDED SERVICE OUTCOMES

2.1 To increase access to the NCSP by providing additional locations where people can access screening.

2.2 To increase access to treatment of Chlamydia infection.

2.3 To increase access for young people to sexual health advice and referral on to specialist services where required.

2.4 To increase clients' knowledge of the risks associated with STIs.

3. CORE SKILLS AND TRAINING

3.1 Training provided in relation to this service is compulsory for every staff member involved in the service. Pharmacy Assistants can offer the screening kit distribution service by attending the training offered, but the treatment part of the service must be provided by accredited pharmacists. A minimum of one pharmacist per pharmacy should attend the training programme to become an accredited pharmacy.

3.2 The pharmacy contractor has the responsibility to ensure that all staff including locums involved in providing the service have appropriate knowledge and are appropriately trained i.e. attendance at a Chlamydia training programme provided by Cambridgeshire Chlamydia Screening Service.

3.3 The pharmacy contractor has the responsibility to ensure that pharmacists and staff involved in the provision of the service are aware of and act in accordance with local protocols.

3.4 The pharmacy contractor has the responsibility to ensure that their service has the recommended quality controls in place and that the service can demonstrate compliance.

3.5 Training will be provided free of charge by the Cambridgeshire Chlamydia Screening Service.

3.6 Pharmacists must have successfully completed the following training packages to become accredited for this service:

CPPE on line training - Sexual Health: testing and treating and Patient Group Directions

It is the responsibility of the Pharmacy Manager to ensure that all pharmacists including locums supplying Chlamydia treatment are accredited.

3.7 Pharmacists and staff providing this service should also be aware of local and national guidance on safeguarding children, as it is possible that people under the age of 16 will request screening.

3.8 The pharmacist will maintain clinical knowledge appropriate to their practice as part of their continuing professional development requirements.

4. SERVICE OUTLINE

There will be three aspects to the service;

- Chlamydia screening
- Condom distribution
- Treatment of infection

Pharmacies must sign up to chlamydia screening to become an accredited site. The treatment of infection and condom distribution part of the service is optional.

4.1 Chlamydia Screening

4.1.1 The pharmacy will offer asymptomatic sexually active males and females less than 25 years of age a Chlamydia screening service; the benefits of screening will be explained. People less than 16 years of age will be provided with the service if deemed Fraser competent. People less than 16 years of age who present for screening and who are not deemed to be Fraser competent will be referred to the Cambridgeshire Chlamydia Screening Programme.

4.1.2 The service will be provided in compliance with Fraser guidance and Department of Health guidance on confidential sexual health advice and treatment for young people aged under 16 years.

4.1.3 The pharmacy staff shall complete the appropriate consent and demographic documentation with people who consent to screening and shall describe the screening process and how results will be communicated to the person.

4.1.4 The person will be supplied with a Chlamydia screening kit and will be encouraged to carry out the test and return this as appropriate.

4.1.5 Partners of laboratory confirmed asymptomatic Chlamydia patients who present for treatment should also be given a screening postal kit.

4.2 Treatment of infection

4.2.1 People aged under 16 years of age should be referred to the Chlamydia Screening Programme for treatment.

4.2.2 Where the pharmacy has opted to provide a treatment service, the pharmacy shall assess the suitability of the person to receive the locally agreed antibiotic treatment, in line with the inclusion and exclusion criteria detailed in the PGD for the administration and supply of Doxycycline, Azithromycin and Erythromycin for Chlamydia. Where appropriate a supply will be made; where a supply of the specific antibiotic is not appropriate, the person should be referred to the Cambridgeshire Chlamydia Screening Programme.

4.2.3 Verbal and written advice on the avoidance of STIs and the use of regular contraceptive methods, including advice on the use of condoms, shall be provided to the person. This should be supplemented by a referral to a service that can provide further advice and care where appropriate.

4.3 Condom distribution

4.3.1 Pharmacies will provide information about the C Card (condom distribution) scheme and signpost clients to where they can sign up to the scheme.

4.3.2 Pharmacies will act as condom supply points for clients registered with the C Card scheme.

4.4 General

4.4.1 The part of the pharmacy used for the provision of the service must provide a sufficient level of safety and privacy (including visual privacy where appropriate), which must be at the level required for the provision of the Medicines Use Review service.

4.4.2 The pharmacy contractor must have a standard operating procedure in place for this service. The pharmacy contractor must ensure that pharmacists and staff involved in the provision of the service are aware of and operate within national and locally agreed protocols.

4.4.3 The pharmacy must maintain appropriate records via the PharmOutcomes web-based system to ensure effective ongoing service delivery and audit. Records are confidential and should be stored securely and for a length of time in line with local NHS and CCC record retention policies.

4.4.4 CCC will monitor and feedback the Chlamydia test kit return rate to individual pharmacies and may investigate where the return rate is consistently low (for example below 25%).

5. CCC RESPONSIBILITIES

5.1 CCC will ensure the materials required, such as Chlamydia screening kits and condoms, will be supplied free of charge to the pharmacy via the Chlamydia Screening Service.

5.2 CCC will provide PharmOuctomes for the recording of relevant service information for the purposes of audit and the claiming of payment. The PharmOutcomes system will be used for recording and reporting activity and will be used to generate non-patient identifiable reports which the CCC commissioning team will use for processing payments.

5.3 CCC will provide up to date details of other services which pharmacy staff can use to refer on service users who require further assistance.

5.4 CCC ensure the provision of training for the scheme and contractor meetings to promote service development and update pharmacy staff with new developments, knowledge and evidence.

5.5 CCC will be responsible for the provision of health promotion and other promotional materials, for example leaflets on STIs, to pharmacies.

5.6 CCC will coordinate the promotion of the service locally, including the development of publicity materials and the use of nationally produced materials, in order to ensure young people and other local healthcare providers are aware that the service is available from local pharmacies. Pharmacies should use these materials to promote the service to the public and should ensure they coordinate their promotional activities with those of the CCC.

6. PHARMACY RESPONSIBILITIES

6.1 The pharmacy will complete all interventions on the PharmOutcomes system.

6.2 The pharmacy has appropriate CCC provided health promotion material available for the user group and promotes its uptake.

6.3 The pharmacy reviews its standard operating procedures and the referral pathways for the service.

6.4 The pharmacy should be able to demonstrate that pharmacists and staff involved in the provision of the service have undertaken CPD relevant to this service and CCC organised training provided by accredited trainers.

6.5 The pharmacy participates in CCC organised audit of service provision where required and will co-operate with the CCC inspection, monitoring and evaluation procedures which may include inspections to evaluate and record the Service Provider's performance.

6.6 The pharmacy co-operates with any locally agreed CCC-led assessment of service user experience.

6.7 The pharmacy will nominate a named individual who will act as a point of contact for this service.

6.8 **Safeguarding**

It is important that practices protect children and adults from avoidable harm (as defined in Safeguarding Children and Adults guidelines) including safeguarding training, training on the Mental Capacity Act and Deprivation of Liberty. A Safeguarding lead should be identified in each pharmacy.

Children's Safeguarding Board
http://www.safeguardingcambspeterborough.org.uk/availabletraining/
http://www.safeguardingcambspeterborough.org.uk/children-board/reporting-concerns/
http://www.safeguardingcambspeterborough.org.uk/children-board/professionals/

Adults Safeguarding Board:
http://www.safeguardingcambspeterborough.org.uk/adults-board/information-for-professionals/cpsabprocedures/
http://www.safeguardingcambspeterborough.org.uk/adults-board/adult-safeguarding-training/

Specific for independent contractors such as pharmacy
http://www.safeguardingcambspeterborough.org.uk/children-board/professionals/safeguardingforgps/

7. DATA RETURNS AND REMUNERATION

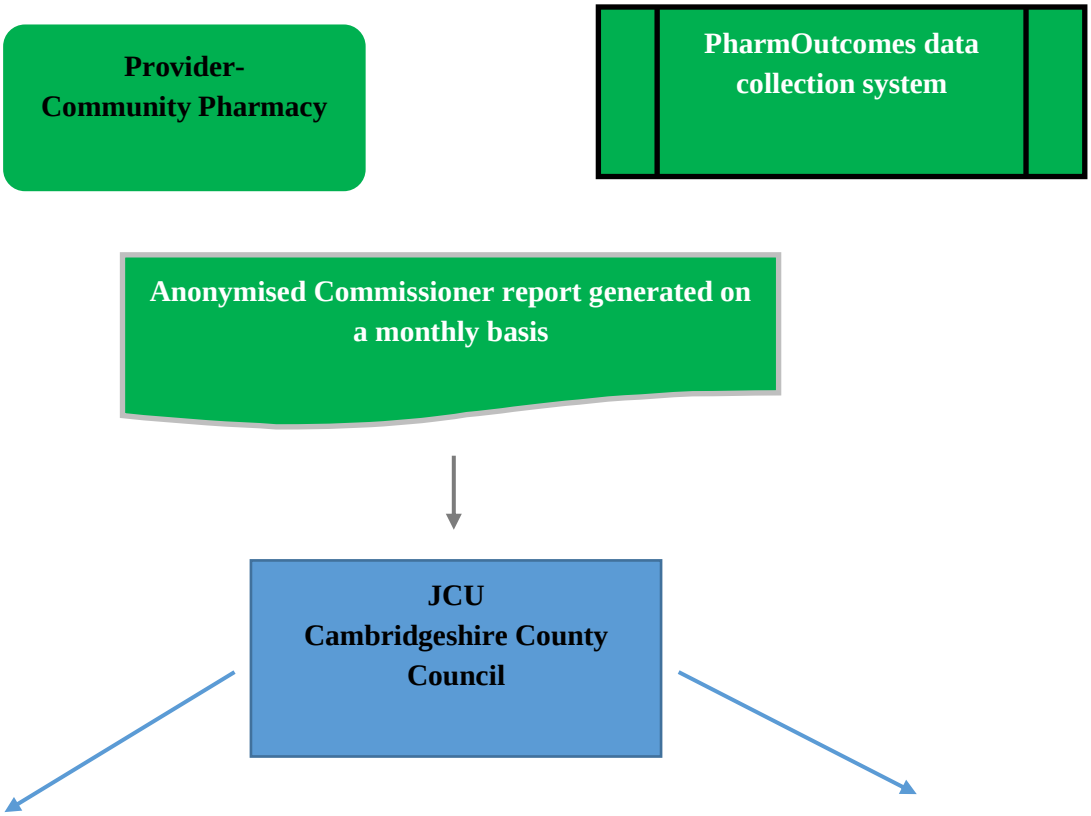
Chlamydia Testing

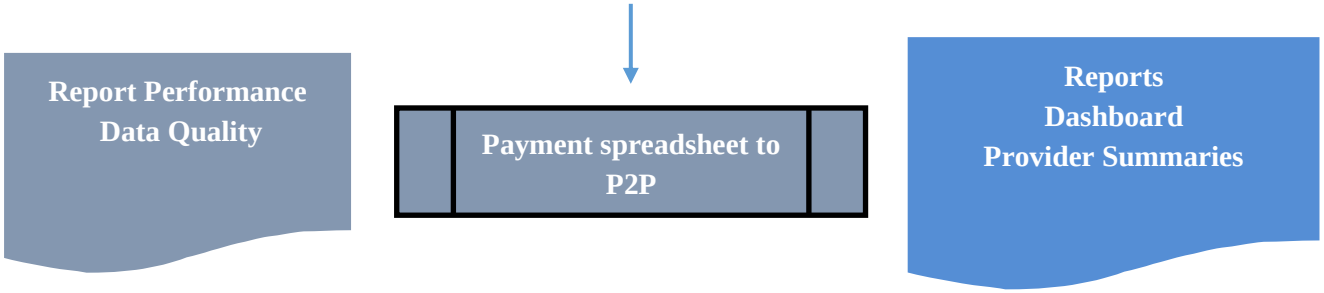
Chlamydia test kit: Pharmacies will be paid **£2.50 for each test kit given out.** Pharmacies are required to complete the appropriate PharmOutcomes template for each kit distributed.

Completed test: This information will be supplied to CCC by the Chlamydia Screening Programme from laboratory reports. Pharmacies will be paid £**5.00 for each valid completed test returned**. Information on test kits returned will be obtained from the Chlamydia Screening Service on a monthly basis.

Pharmacies will be paid £7.50 per treatment consultation. Plus reimbursement of the drug cost as set for the financial year as per the BNF values on 1st April 2019. Tariff costs will be reviewed and renewed on an annual basis

Community Pharmacy - Chlamydia Screening Data Flow




Report Performance
Data Quality
Payment spreadsheet to
P2P
Reports
Dashboard
Provider Summaries

Lot 2: Public Health Community Pharmacy Contract Emergency Hormonal Contraception

Service Specification: COMMUNITY PHARMACY, EMERGENCY HORMONAL CONTRACEPTION (EHC) SERVICE 2019-2020

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1. SERVICE DESCRIPTION

1.1 Emergency contraception (EC) may **only** be supplied by an accredited pharmacist. Medicine counter staff must be trained to refer each request for emergency contraception to the pharmacist(s). It is the responsibility of the Pharmacy Manager to ensure that all pharmacists, including locums, supplying EC are accredited.

1.2 The pharmacy must be able to supply emergency contraception during opening hours of the pharmacy on at least 4 days of the week, one of which will preferably be a Saturday.

1.3 Pharmacists will supply Emergency Hormonal Contraception (EHC) when appropriate to clients in line with the requirements of the Patient Group Direction (PGD) 2018-2021 for the supply of EHC by Community Pharmacists.

1.4 Pharmacies will offer a user-friendly, non-judgmental, client-centred and confidential service. The supply will be made free of charge to the client at Cambridgeshire County Council's (CCC) expense.

1.5 Pharmacists will link into existing networks for community contraceptive services so that women who need to see a doctor can be referred on rapidly.

1.6 Clients excluded from the PGD criteria will be referred to another local service that will be able to assist them, as soon as possible, e.g. GP or community contraception service.

1.7 The pharmacy will provide support and advice to clients accessing the service, including advice on the avoidance of pregnancy and sexually transmitted infections (STIs) through safer sex and condom use, advice on the use of regular contraceptive methods and provide onward signposting to services that provide long-term contraceptive methods and diagnosis and management of STIs.

2. AIMS AND INTENDED SERVICE OUTCOMES

2.1 To increase the knowledge, especially among young people, of the availability of emergency contraception and contraception from pharmacies.

2.2 To improve access to emergency contraception and sexual health advice.

2.3 To increase the use of EHC by women who have had unprotected sex.

2.4 To help contribute to a reduction in the number of unplanned pregnancies in the client group.

2.5 To refer clients, especially those from hard to reach groups, into mainstream contraceptive services.

2.6 To increase the knowledge of risks associated with STIs.

2.7 To refer clients who may have been at risk of STIs to an appropriate service.

2.8 To strengthen the local network of contraceptive and sexual health services to help ensure easy and swift access to advice.

3. CORE SKILLS AND TRAINING

In order to achieve accreditation, the pharmacist(s) must have satisfactorily completed the following learning packages:

- CPPE on line training - Emergency Hormonal Contraception
- CPPE on line training - Patient Group Directions
- CPPE on line training - Safeguarding Children

It is the responsibility of the Pharmacy Manager to ensure that all pharmacists including locums supplying EC are accredited.

The pharmacist will maintain clinical knowledge appropriate to their practice as part of their continuing professional development requirements.

4. SERVICE OUTLINE

4.1 The main client group is women under the age of 50 years who might require emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.

4.2 The part of the pharmacy used for provision of the service provides a sufficient level of privacy (ideally at the level required for the provision of the Medicines Use Review service) and safety and meets other locally agreed criteria.

4.3 A service will be provided that assesses the need and suitability for a client to receive EHC, in line with the PGD. Where appropriate a supply will be made; where a supply of EHC is not appropriate, advice and referral to another source of assistance, if appropriate, will be provided. Clients who have exceeded the time limit for EHC will be informed about the possibility of use of an IUD and should be referred to a local service as soon as possible.

4.4 Inclusion and exclusion criteria, which are detailed in the PGD, will be applied during provision of the service.

4.5 The service will be provided in compliance with Fraser guidance and Department of Health guidance on confidential sexual health advice and treatment for young people aged under 16.

4.6 Verbal and written advice on the avoidance of STIs and the use of regular contraceptive methods, including advice on the use of condoms, will be provided to the client. This should be supplemented by a referral to a service that can provide treatment and further advice and care.

4.7 The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service, including sensitive, client centred communication skills.

4.8 The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service are aware of and operate within local protocols.

4.9 The pharmacy must maintain appropriate records to ensure effective ongoing service delivery and audit. Records will be confidential and should be via the PharmOutcomes web-based platform and for a length of time in line with local NHS and CCC record retention policies. The PharmOutcomes system will be used for recording and reporting activity and will be used to generate non-patient identifiable reports which the CCC commissioning team be use for processing payments.

4.10 Pharmacists may need to share relevant information with other healthcare professionals and agencies, in line with locally determined confidentiality arrangements, including, where appropriate, the need for the permission of the client to share the information.

4.11 The pharmacist may make a supply to a girl s/he believes to be under 16; however, the pharmacist must assess her 'competence' under the Fraser Guidelines.

4.12 The client is able to make an informed choice about whether to use emergency contraception and which method might be most suitable.

4.13 The client is safely supplied with emergency contraception.

4.14 If the client is under 25 they are supplied with a Chlamydia test pack and advised to complete it and send it off.

4.15 The client is made aware of the need to consider a longer term method of contraception and the support and follow-up available to them through their GP or Family Planning Services.

4.16 The client is made aware of any possible risk of Sexually Transmitted Infections and the support and follow-up available to them through their GP, Family Planning Services or GUM clinic.

4.17 All requests for emergency contraception must be dealt with sensitively and discreetly with due regard for the client's right to privacy. Medicine Counter staff must refer all such queries to the accredited pharmacist without delay.

4.18 The pharmacist must personally speak with and counsel the person requesting emergency contraception **although advice may be given over the telephone.** The pharmacist must obtain the information outlined in the pro-forma before making any recommendation regarding emergency contraception.

4.19 The product may only be supplied for use at the time of purchase and should not be supplied for possible future use.

4.20 Patients should be provided with appropriate information leaflets.

5. LABELLING AND RECORD KEEPING

5.1 Any EHC pack supplied to take away should be labelled with the following information:

- The pharmacy address
- 'Keep out of the reach of children'
- Directions for use
- The name of the client
- Date of supply

5.2 The relevant template should be completed for each client on PharmOutcomes, paying particular attention to the assessment of need and clinical assessment. A note of any additional information and the action taken by the pharmacist should also be made on the record form. A note of supply may also be made in the client's patient medication record. Client records must be kept by the accredited pharmacy for 8 years if the client is believed to be over 16 and until the client's 26th birthday if they are believed to be under 16.

5.3 The relevant template should be completed for each client on PharmOutcomes with the number of Chlamydia screening packs given out that should be sent monthly to CCC for payment. Postal Chlamydia screening packs will be supplied free of charge to pharmacies by the Chlamydia Screening Programme.

5.4 All records should comply with the requirements of the RPSGB's Standards of Good Professional Practice. Whilst rare, all serious Adverse Drug Reactions (ADRs) should be reported, even if the effect is well recognised (see British National Formulary (BNF) for supporting information). ADRs should be reported to The Committee for the Safety of Medicines, using the yellow ADR card system. Cards are available in the BNF. A client presenting with a suspected ADR should be referred to a doctor for further investigation.

6. CAMBRIDGESHIRE COUNTY COUNCIL RESPONSIBILITIES

6.1 The accredited pharmacist will not be working in isolation and must feel confident to refer to other sources of information and support services including other participating pharmacists, Family Planning Consultants and Nurses, GP's, and child protection officers subject to the requirement for confidentiality.

6.2 CCC will provide PharmOutcomes for the recording of relevant service information for the purposes of audit and the claiming of payment.

6.3 CCC will provide up to date details of other services which pharmacy staff can use to refer service users who require further assistance. The information should include the location, hours of opening and services provided by each local service provider.

6.4 CCC will be responsible for the promotion of the service locally, including the development of publicity materials, which pharmacies can use to promote the service to the public.

6.5 CCC will be responsible for the provision of health promotion material, including leaflets on EHC, long-term contraception and STIs to pharmacies.

6.6 CCC will be responsible for the distribution of Chlamydia testing kits and providing support to pharmacies to enable the effective provision of these kits to women under 25 years of age.

7. PHARMACY RESPONSIBILITIES

7.1 The pharmacist must ensure that their professional indemnity cover is either provided by the National Pharmaceutical Association (NPA) or another organisation that have confirmed that this activity will be included in their policy.

7.2 The service should be provided in a pharmacy, which must have a suitable area for consultation with patients. This may be a quiet area within the shop, where privacy can be maintained, rather than a separate room.

7.3 The pharmacy will be required to ensure that there is sufficient trained staff to be able to deliver the service according to this specification.

7.4 Also it is the responsibility of the pharmacy to ensure that there is sufficient medication, support materials and Chlamydia testing kits to be able to deliver the service.

7.5 The pharmacy will be required to designate space to display a poster giving information on emergency contraception.

7.6 The client should always be advised to talk to her GP or local family planning clinic, regardless of whether a supply is made. However, where the pharmacist, on the basis of the information obtained, is not certain that emergency contraception can be supplied, the client should be referred to a doctor immediately (refer to clinic lists).

7.7 Emergency contraceptives are not suitable for repeated use as they have a higher failure rate than regular oral contraceptives. Patients should be told to visit their GP or family planning clinic if menstruation is late, missed or lighter than usual or if there is any unusual pain. It may be advisable for the client to seek advice earlier about on-going contraception.

7.8 Pharmacists should use their judgement in terms of the best way to phrase the offer of a Chlamydia Test Kit. Acceptance rates are usually highest when it is phrased in a routine way, for example "we ask everyone who is given EHC in your age group to complete a Chlamydia test. Here is a kit for you"

8. FRASER GUIDANCE

8.1 The pharmacist should make and record a judgement about the competence according to Fraser Guidance of every client who is believed to be under 16. This includes:

8.1.1 Whether the young person understands the potential risks and benefits of the treatment and advice given.

8.1.2 The value of parental support is discussed, with the health professional encouraging the young person to inform parents/carers of the consultation and explore the reasons if the patient if unwilling to do so. They must assure the young person that their confidentiality will be respected whether they inform their parents/carers or not unless there is any suspicion of abuse.

8.1.3 Whether the young person is likely to have or continue to have sexual intercourse without contraception.

8.1.4 Whether the young person's physical or mental health is likely to suffer if they do not receive contraceptive advice or treatment.

8.1.5 Whether it is in young person's best interest to provide contraceptive advice and treatment without parental consent.

8.2 Taking the above into consideration the pharmacist should decide if the young person is competent to receive advice and treatment. The consultation will be governed by the same terms of confidentiality whether or not the health professional considers the young person competent.

8.3 When a young person is judged not to be competent she should be referred to their GP or Family Planning doctor.

8.4 When seeing clients under the age of 16, the pharmacist(s) is required to have regard to child protection issues. Pharmacist should act in accordance with Cambridgeshire County Council's Child Protection Guidelines. Any pharmacist who has concerns about a young person should seek advice from the most appropriate professional which may be a senior colleague, the Named Nurse or Doctor for Child Protection or Social Services. In the first instance the clients name and address should not be used, if asking for advice.

Advice may be obtained by contacting the child protection contacts in the PGD.

Safeguarding Children guidelines can be obtained via this link:
http://www.proceduresonline.com/cambridgeshire/scb/

9. Safeguarding Children and Adults

It is important that practices protect children and adults from avoidable harm (as defined in Safeguarding Children and Adults guidelines) including safeguarding training, training on the Mental Capacity Act and Deprivation of Liberty. A Safeguarding lead should be identified in each pharmacy.

Children's Safeguarding Board
http://www.safeguardingcambspeterborough.org.uk/availabletraining/
http://www.safeguardingcambspeterborough.org.uk/children-board/reporting-concerns/
http://www.safeguardingcambspeterborough.org.uk/children-board/professionals/

Adults Safeguarding Board:
http://www.safeguardingcambspeterborough.org.uk/adults-board/information-for-professionals/cpsabprocedures/
http://www.safeguardingcambspeterborough.org.uk/adults-board/adult-safeguarding-training/

Specific for independent contractors such as pharmacy
http://www.safeguardingcambspeterborough.org.uk/children-board/professionals/safeguardingforgps/

10. SERVICE MONITORING

10.1 Performance monitoring will be in line with service standards and the pharmacy may be monitored on the following:

- Availability of appropriate material to support the provision of advice to the client group.
- Maintenance of accurate records as required by the PGD.
- Reviews of standard operating procedures and updates as necessary.

- Participation in the bi-annual review of service provision including any updated developments.
- The outcomes of any patient experience surveys, feedback or complaints.
- The proportion of the number of women under 25 who received EHC and have been given a Chlamydia screening pack.
- The proportion of Chlamydia screening packs that is returned to the screening service from women under 25.
- A review of the number of occasions when an accredited pharmacist was not available to provide the services at the pharmacy.

10.2 Information outlining the process of the service must be cascaded to other pharmacy staff.

10.3 Non-pharmacist staff must be trained to refer clients to an accredited pharmacist. Where an accredited pharmacist is unavailable on the premises, clients should be signposted to an appropriate alternative service.

10.4 Non-pharmacists may not be accredited nor are they allowed, by law, to supply via this patient group direction (PGD). Pharmacies should inform the CCC as soon as possible in situations where an accredited pharmacist will no longer be available to provide the service.

10.5 Pharmacies should inform the CCC as soon as possible in situations where the designated pharmacy signatory is no longer able to retain responsibility for the SLA operating in a given accredited pharmacy, to enable transfer of designated signatory status or termination of the agreement.

11. QUALITY INDICATORS

11.1 The pharmacy has appropriate CCC provided health promotion material available for the client group actively promotes its uptake and is able to discuss the contents of the material with the client, where appropriate.

11.2 The pharmacy reviews its standard operating procedures and the referral pathways for the service on an annual basis.

11.3 The pharmacy participates in an annual CCC organised audit of service provision.

11.4 The pharmacy co-operates with any locally agreed CCC-led assessment of service user experience.

11.5 The pharmacy offers each woman under 25 years of age a Chlamydia test Kit when she requests the EHC service.

12. DATA RETURNS AND REMUNERATION

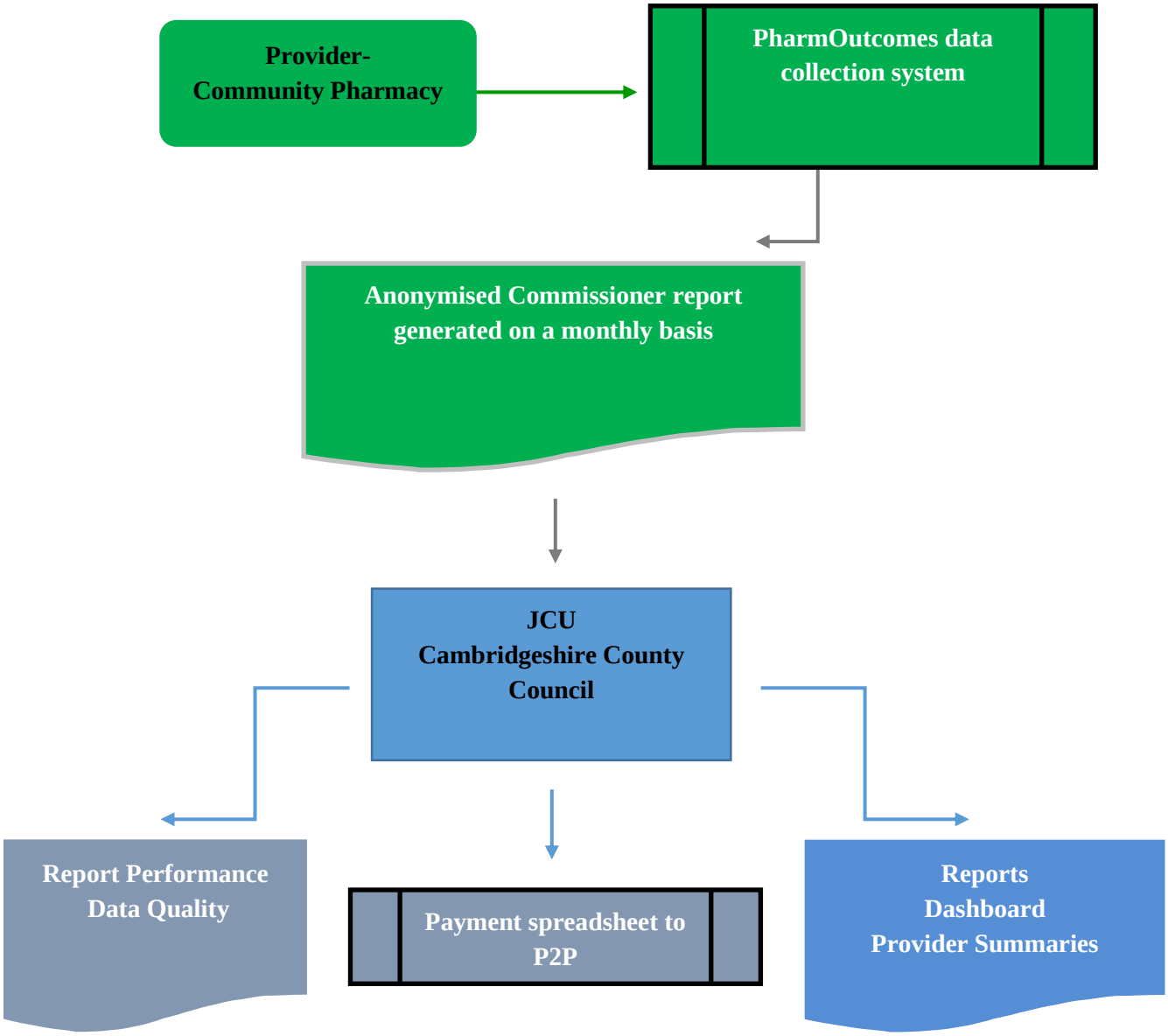
Consultations: The payment of **£13 per consultation** will be available regardless of whether a supply of Levonelle (Levornorgestrel) or Ulipristal was made.

Prescribing: The pharmacy will be reimbursed the Tariff price of April 2019 Levonorgestrel 1.5mg tablets £5.20p or Ulipristal 30mg tablet.£14.05p

Chlamydia test kits: Pharmacies will be paid **£2.50 for each Chlamydia test kit given out.**

Payment will be made by the CCC based on extracted commissioner's report on Pharmacoutcomes.

Community Pharmacy Emergency Contraception Data Flow



Lot 3: Public Health Community Pharmacy Contract Smoking Cessation

Service Specification: Smoking Cessation 2019-2020

Contents

Context Update

Cambridgeshire County Council and Peterborough City Council commission stop smoking services from Community Pharmacies for their local populations. Both local authorities are working more closely together which reflects the footprint of the Cambridgeshire and Peterborough Clinical Commissioning Group. Consequently there are a number of Joint Commissioning Units emerging including the Cambridgeshire and Peterborough Public Health Joint Commissioning Unit (JCU). This Public Health JCU launched May 1 2017, commissioning responsibilities will include the services that are provided by primary care. The aim is to standardise the commissioned primary care services across the CCG footprint. Although the JCU will work across the two local authority areas individual Community Pharmacy contracts will be contracted by the local authority where they are geographically located. Staff from the JCU will continue to support Community Pharmacies where appropriate as well have a performance management function.

1. Service Description

Smoking remains the main cause of preventable death in England and it is the primary reason for the gap in healthy life expectancy between the rich and poor. The adult smoking prevalence in Cambridgeshire is 14.5% (APS 2017) and the prevalence amongst those who are routine and manual is 22.8%. However the prevalence varies across the county with

the prevalence in the district of Fenland at 16.8% (APS 2017) and the smoking prevalence within the routine and manual population at 23.5%. The smoking prevalence in England is 14.9% and the East of England's 14.2%.
Stop smoking activity will support improvements against relevant outcomes and indicators with in the Public health Outcome's Framework including:

- Reducing the smoking prevalence in Adults (over 18)
- Reducing the prevalence of smoking in young people and in particular those who are recorded as smokers at the age of 15 years or under
- Reducing the smoking status at the time of delivery

The aim of this service specification is to indicate the requirements for the Community Pharmacy Stop Smoking Service that supports smokers in Cambridgeshire to make a quit attempt in line with NICE Guidance **and the Standard Treatment Programme from the National Centre for Smoking Cessation Training (NCSCT).** It fully reflects NICE Guidance in terms of the intervention and DH requirements for monitoring.

The Cambridgeshire Community Pharmacy Stop Smoking Contract is for the following:

- The provision of a structured evidence based 4 week quit attempt as part of the 12 week treatment programme that includes setting a quit date and support for behavioural change in conjunction with pharmacotherapy indicated in this specification. This does not include: 'cut down to quit' programmes, or the long term use of NRT.

- The provision of a structured evidence based 4 week quit attempt as part of the 12 week treatment programme that includes setting a quit date and support for behavioural change in conjunction with an electronic cigarette. E-cigarettes are not currently available on prescription but can be purchased by the client to support their quit attempt.

  Payment will be made when stop smoking services are delivered by Community Pharmacy in accordance with this service specification and related summary data submitted via PharmOutcomes software which has been commissioned by the Public Health Joint Commissioning Unit.

Payments will not be made for behavioural support that has been provided to clients who are not smoking, but request support for stopping their use of electronic cigarettes.
Payments will not be made to the pharmacy for referring a patient to the stop smoking service.

2. Requirements of the Service

This service should be offered to **all identified smokers over the age of 12 years old** who use the pharmacy.

A structured stop smoking support programme for a quit attempt should be provided and should include the following elements:

2.1 **Assessment:** An assessment of a person's readiness to make a quit attempt and use of appropriate treatments.

2.2 **Setting a quit date** with the patient which marks the commencement of the patient's four week quit attempt.

2.3 **Pharmacological treatments** should be prescribed in line with NICE Guidance and local protocols. An initial two weeks supply will be prescribed and repeated after the first two weeks of the quit attempt and every two – four weeks thereafter for a typical treatment period of up to twelve weeks. Clients are to be informed of the pharmacological treatments and (evidence-based and licensed for use for smoking cessation) and options discussed prior to prescribing.

2.4 **Data should be recorded via the web- based platform PharmOutcomes system and all patients must be asked to consent for treatment and data sharing where appropriate.**

2.5 **Patient Contact**: The initial assessment should be a minimum of 20 minutes duration, and if the patient/client sets a quit date then a minimum of 10 minutes should be allocated to follow up appointments. In total it is expected that the patient is given at least 1.5 hours of clinical time during the quit attempt to ensure continued monitoring, client compliance and ongoing access to medication. It is acknowledged that some clients do not need weekly consultations; *but there should be a* **minimum of three consultations** including preparation for setting a quit date. This can include telephone contact but it is recommended that the first and final contacts of the 4 week quit attempt should be face to face so that CO reading can be taken.

2.6 **Active management of lost to follow ups** should include the following actions:

- Any clients failing to attend a particular session should be followed up **at least three times** and encouraged to continue the programme in accordance with the agreed protocol.
- People not wishing to initially engage or those who choose not to complete the programme may be offered appropriate health literature or referral to an alternative stop smoking service.
- Clients who are recorded as 'lost to follow up' at the four week stage, should be coded and their data returned. No payment is made for clients with this outcome.

2.7 **Recording Smoking status at four weeks post quit date** can be assessed by the following:

- Self-reported smoking status at 4 weeks post quit date
- Carbon Monoxide test validation at 4 weeks post quit date
- Not Quit at 4 weeks post quit date
- Lost to follow up at 4 weeks post quit date

Please note: On receipt of clients details who were 'Lost to follow up or Not quit' at 4 weeks post quit date CAMQUIT will continue to contact the client to seek a smoking status or further engage the client with a quit attempt/ a suitable service.

2.8 **Completing the twelve week standard treatment programme** by providing regular behavioural support sessions, CO monitoring and NRT prescriptions from 4 week stage to 12 weeks.

2.9 **Data quality**

There should be a strong emphasis on collecting and reporting gold standard data and should be attempted for all quit attempts. Services are expected to meet the minimum quality standards that define best practice locally:

1. All smokers set a quit date at the first or second appointment.
2. A minimum quit rate (success rate) of 50%.
3. At least 85% of quits to be CO validated. Success should be validated by a CO (Carbon Monoxide) monitor reading of less that 6ppm at the 4 week stage.

4. At least 45% of quits to be achieved in Routine and Manual occupational groups.
5. Lost to follow up rate to be less than 15% of smokers who set a quit date.
6. All occupational codes to be recorded.
7. Smokers who have previously failed to quit at the GP's own or Pharmacy Service or who have complex needs (such as a severe mental health condition) should be offered a referral to CAMQUIT.
8. All Services to offer NRT, varenicline or bupropion (GP prescription only) as first-line treatments (if clinically appropriate).
9. All Service Users are to be given an opportunity to evaluate the Service that they have received.

3. Core skills and Training

3.1 **Training**
All staff should be trained to Department of Health, NICE & NCSCT standards and use evidence based approved methodology (training programmes are designed in line with guidance provided by the National Centre for Smoking Cessation and Training).

3.2 Smoking cessation training is compulsory for every staff member involved in the service. Pharmacy Assistants can offer the service by attending the stop smoking training provided by the Specialist Smoking Cessation leads in Cambridgeshire and Peterborough as specified by the Commissioner. A minimum of one pharmacist per pharmacy and one pharmacy assistant should attend the training programme to become an accredited pharmacy.

3.3 The pharmacy contractor has the responsibility to ensure that all staff including locums involved in providing the service are appropriately trained i.e. attendance at a Cambridgeshire organised smoking cessation training programme.

3.4 The pharmacy contractor has the responsibility to ensure that pharmacists and staff involved in the provision of the service are aware of and act in accordance with the Service Specification, Cambridgeshire County Council protocols, CAMQUIT best practice guidance and NICE guidance.

3.5 The pharmacy contractor has the responsibility to ensure that their service has the recommended quality controls in place and that the service can demonstrate compliance.

3.6 Training will be provided free of charge by the local coordinating stop smoking services and will be provided by accredited trainers. Advisors must attend annual update training.

3.7 All advisors are encouraged to access the nationally accredited certification which is available free of charge via the National Centre for Smoking Cessation Training website www.ncsct.co.uk .

3.8 It is recommended that women who are currently pregnant should only be seen by a Pharmacy advisor who has accessed the CAMQUIT specialist pregnancy training and it is the Pharmacist responsibility to supply and monitor smoking cessation medication and for the treatment and care of the pregnant smoker.

4. Consultations and Gold Standard service

4.1 The service requirements are summarised in the table below.

One-to-one behavioural support sessions (minimum support for the first six weeks)

Session	Minimum time allocated (minutes)
Session 1: Pre-quit	30
Session 2: Quit date	20
Session 3: 1 week post-quit	15
Session 4: 2 weeks post-quit	15
Session 5: 3 weeks post-quit	15
Session 6: 4 weeks post-quit*	15
Total	1 hour 50 minutes

* Further sessions may be provided as per local protocol. Clients will need to be able to access the full course of their chosen stop smoking medicine(s) (see page 32).

	SPECIFICATION	WHEN
1a	Initial assessment- Brief advice (5 minutes) ▪ Assessment of person's readiness to make quit attempt and use appropriate treatments	Can be done separately or together. Ideally give patient information in assessment and ask patient to come back for consultation to set quit date
1b	Initial consultation (30 minutes) ▪ Set quit date ▪ Supply 4 weeks medication however only dispense 2 weeks at a time. Alternatively discuss the use of an electronic cigarette and where they can purchase the product. ▪ Complete monitoring form ▪ Carbon monoxide (CO) test validation ▪ Complete the patient records notes on PharmOutcomes	
1c	Follow up (15 minutes) ▪ Second medication supply	Weeks 1-3 post quit date
1d	Follow up (15 minutes) • Medication supply	Weeks 1-3 post quit date
1e	Follow up (15 minutes) • Medication supply	Weeks 1-3 post quit date
2	4 week follow up (15 minutes) ▪ Self-reported smoking status ▪ CO test validation ▪ Further supply of medication if appropriate ▪ Complete the patient records notes on PharmOutcomes	4 weeks post quit date
3	If client has QUIT 5-8 weeks after ***QUIT*** date (15 minutes) ▪ Further supply of medication for 4 weeks if appropriate ▪ CO test (optional) ▪ Complete patient notes ▪ Complete the patient records notes on PharmOutcomes	5-8 weeks after Quit date

4	9-12 weeks after ***QUIT*** date (15 minutes) ▪ Further supply of medication for 4 weeks if appropriate ▪ CO test (optional) ▪ Complete patient notes ▪ Complete the patient records notes on PharmOutcomes	9-12 weeks
N.B.		
If client has **NOT QUIT at the four week stage** start from initial consultation stage again, re-assess their readiness to Quit and negotiate a new quit date (15-30 minutes) ▪ Set a new quit date ▪ Supply 4 weeks medication however only dispense 2 weeks at a time. Alternatively discuss the use of an electronic cigarette and where the client can purchase them from. ▪ Complete a new monitoring form ▪ CO test validation ▪ Complete the patient notes		

4.2 Access routes to this service will be determined locally, however they could include:

- Pharmacy referral as a result of the 'Promotion of healthy lifestyles (Public Health)' or 'Signposting' essential services
- Direct referral by the individual
- Referral by another health or social care worker
- Referral from the specialist service
- Referral via the National Referral system at the acute local hospitals

4.3 The ***initial assessment*** should include:

- An assessment of the person's readiness to make a quit attempt
- An assessment of the person's willingness to use appropriate treatments and the treatment programme

4.4 The ***initial consultation*** should include:

- A carbon monoxide (CO) test and an explanation of its use as a motivational aid
- A description of the effects of smoking and second hand smoke on children and adults
- A description of the main benefits of stopping smoking
- A description of the main features of tobacco withdrawal and the common barriers to quitting
- Identify treatment options that have proved effective
- Describe what a typical treatment programme will look like, its aims, length, how it works and its benefits
- Maximise commitment to quit date
- Apply appropriate support strategies to help the person stop smoking

Conclude with an agreement on the chosen treatment pathway and process a prescription for their chosen stop smoking medication for 4 weeks (to be dispensed at fortnightly intervals), ensuring the person understands the on-going support, request consent to follow-up by the Advisor and monitoring arrangements, the development of a personal behaviour strategy for stopping smoking. Give personal information leaflet.

4.5 Evidence suggests that week's 1-4 are crucial to the success of a quit attempt, so it is recommended that the practice smoking cessation service offers as much support to the client during this time to have the greatest success i.e. face to face &/or telephone support weekly from the initial consultation to the four week follow up.

4.6 The ***4-week follow up*** should include self-reported smoking status, followed by a CO test for validation. Smokers would normally be expected to attend regular sessions and at the session 4 weeks after the quit date the client can be classed as a quitter if they have not had a puff of a cigarette at all in the past two weeks.

Although face to face consultations are considered to be the best way to engage with a client, telephone consultations, email and text messaging are also acceptable forms of communication.

4.7 People not wishing to initially engage or those who choose not to complete the programme may be offered appropriate health literature or referral to an alternative stop smoking service.

4.8 The Advisor will have the responsibility to follow up any clients failing to attend a particular session and encourage them to continue the programme. This should be in accordance to an agreed protocol.

5. Prescribing and Supply of Nicotine Replacement Therapy (NRT) options

5.1 If considered appropriate, the pharmacist may supply NRT for the initial four weeks of the treatment programme (to be dispensed every two weeks) and will advise on its use. Supply of treatment must be recorded on PharmOutcomes and client notes sheet. After the initial four weeks the client will be reassessed for a further supply of NRT and reassessed again at the eight week stage for a final prescription. Supply of NRT should be in line with the Cambridgeshire & Peterborough prescribing policy.

5.2 If patients are exempt from NHS prescription charges then there is no charge to the client for supply of NRT through this scheme.

5.3 Clients accessing the service who are not exempt from prescription charges will be required to pay one prescription charge for each product type, for every 4 week cycle of NRT supplied e.g. Nicorette patches and Nicorette gum would incur two charges. However, Nicorette 15mg patch followed by 10mg patch would incur one charge provided it is within the same month. The cost of NRT will be reimbursed to the pharmacy through PharmOutcomes.

Please note: clients on two products a month should be advised that it would be cheaper to pay their prescription charges via the NHS prepayment system.

5.4 Combination therapy: combination of NRT products has been shown to have an advantage over using just one product. Although most combinations are acceptable, this should be discussed and assessed on an individual basis with the client; the most common combination being the NRT patch with an oral product. Where clients

are using combination therapy and are not exempt from prescription charges the client should pay one prescription charge per item for each four week supply.

5.6 There is not currently a mechanism to supply Zyban (Bupropion) or Champix (Varenicline) without a prescription. If the client is interested in using either of these smoking cessation treatment choices as an aid to stopping smoking they should be referred to their GP for a medical assessment, regular medication monitoring and continued prescription, you can provide them with behavioural support and the pharmacy advisor should record the details of the intervention as normal on the monitoring form and records sheet.

5.7 Follow up consultations, in line with NICE guidelines, should be agreed with the client and will include smoking status validation using a CO test. A further supply of NRT treatment could be made at these consultations. Consultations can be made via the telephone and a face to face appointment agreed with the client to establish a CO reading.

5.8 If the quit attempt is successful they should be recorded as 'Quit' at the 4 week stage. The client should be assessed on an individual basis and offered NRT for an additional 8 weeks (at 4 weekly intervals) making the total amount of NRT prescription a 12 week course. Continued use of the NRT product is proven to increase a success rate and supports the client to become smoke free long term.

5.9.1 If the quit attempt is not successful at the 4 week stage, the client should be recorded as 'Not Quit' and a new assessment and quit date set, where appropriate. The Department of Health have set out in the 'Monitoring Guidance' that there needs to be no set time duration between quit attempts, however the advisor should use their professional judgement when assessing the clients readiness to change before setting a new quit attempt and if the client has had two failed quit attempts the client should be referred to the local stop smoking and lifestyle services.

5.9.2 In 2015 Public Health England said 'E-cigarettes are significantly less harmful to health than tobacco and have the potential to help smokers quit smoking'. Electronic-cigarettes can be an effective tool as part of the quitting journey alongside the local stop smoking service. Smokers accessing the stop smoking services can use an electronic cigarettes as part of their quit attempt but as they are not classified as a medication are not available via an NHS prescription. The clients is required to source and purchase their own electronic cigarette.

6. NRT Voucher scheme

6.1 As part of the community pharmacy scheme service the contractor is required to dispense NRT upon receipt of a valid NRT Voucher. Clients will be receiving behavioural support from an external provider; therefore the contractor is NOT required to provide additional support.

6.2 Pharmacies will supply NRT on receipt of a voucher from an authorised individual as directed on the voucher. Pharmacies will confirm that the NRT has been supplied as directed and will the medication dispensed on the PharmOutcomes system provided by Cambridgeshire County Council Commissioners. The Joint Commissioning team have access to the 'Commissioners only' element of the system which doesn't contain any patient's identifiable information.

6.3 All clients accessing this scheme will be provided with stop smoking advice by the smoking cessation advisor completing the voucher. Pharmacies will only be required to supply the required product. Patients should be directed back to their smoking cessation advisor for further stop smoking advice or to obtain another voucher for NRT. This is also an opportunity for the Pharmacist to offer the pharmacy scheme if this option is easier for the client.

6.4 The EC Labelling and Leaflet Directive applies to all NRT supplied. The pack should be labelled with the following information:

- The address of the clinical area where the supply was made
- 'Keep out of the reach of children'
- Directions for use
- The name of the patient
- Date of supply

6.5 If the voucher **has not** been signed by the authorised smoking cessation advisor then the supply **should not** be made and should be signposted back to their original advisor or could be signed up on the community pharmacy scheme.

6.6 Vouchers will be valid for two weeks from the date stated by the Smoking Cessation Advisor. Clients who present an out of date voucher should be signposted back to their original advisor or can be signed up on the community pharmacy scheme if this is a suitable programme for the client.

6.7 NRT supplied should be in accordance with the dispensing essential service.

6.8 If the directions on the voucher are not clear then the smoking cessation advisor should be contacted for clarification.

6.9 If patients are exempt from NHS prescription charges then there is no charge to the client for supply of NRT through this scheme. Clients accessing the service who are not exempt from prescription charges will be required to pay one prescription charge per product for each 2 week cycle of NRT supplied. The cost of NRT will be reimbursed to the pharmacy through the voucher minus any prescription charges.

6.10 NRT products are licensed for over 12 year olds. As of Public Health's commitment to reduce the prevalence of smoking in young people, the JCU and local stop smoking services supports the school nurse team to provide NRT products via the voucher scheme after an assessment and Fraser Competency assessment.

6.11 It is the Pharmacists responsibility for the treatment of the smoker and therefore he/she should only dispense the product suggested on the voucher should they deem it appropriate to do so.

7. Record Keeping

7.1 The pharmacy should maintain appropriate records which includes detailed clinical notes via the web-based software PharmOutcomes which has been commissioned for recording all Public Health Interventions in Cambridgeshire & Peterborough. A completed record consists of the minimum data set as defined within the ´NHS smoking cessation services: service and monitoring guidance'.

7.2 Client record forms should be kept via PharmOutcomes following the appropriate security/Information Governance guidance. Old records should be stored in a locked cabinet and archived appropriately.

7.3 All monitoring details should be completed, in full and the outcome at the four week stage clearly marked to avoid any delays in payment. Cambridgeshire County Council will process the service & prescription payments through the Commissioner portal of the PharmOutcomes system.

7.4 Data for people setting a quit date between 1st April 2019 and 31st March 2020 must be followed and accurate on the system by the 1st June 2020. Any data received after this date, for that reporting period will not be used for reporting purposes and reimbursement will not be made by Cambridgeshire County Council.

7.5 2019-20 reporting year begins on 1st April 2019 and finishes on 31st March 2020.

8. Advisor Absences

8.1 Wherever possible continuity of care should be maintained.

8.2 If the advisor is unexpectedly unavailable for a returning client then the pharmacy staff will telephone the client(s) to offer an alternative advisor if available or cancel and rearrange any appointments.

9. Commissioner Responsibilities

9.1 The materials and equipment required to start the service, including CO monitors and disposable mouthpieces ***starter kit***, are supplied free of charge to the pharmacy by the Council's commissioned specialist stop smoking service CAMQUIT.

9.2 Cambridgeshire County Council reimburses the pharmacy for the cost of NRT based on information that the Pharmacy sends.

9.3 The Commissioner provides a platform (Pharmoutcomes) for the recording of relevant service information for the purposes of audit and the claiming of payment.

9.4 The Commissioner will support the promotion of the services locally, including the development of publicity materials, which pharmacies can use to promote the service to the public.

9.5 The Stop smoking service CAMQUIT provides details of relevant referral points which pharmacy staff can use to signpost service users who require further assistance.

10. Pharmacy Responsibilities

10.1 The pharmacy will complete all Public Health interventions on PharmOutcomes' web based system which has been commissioned by the Joint Commissioning Unit.

10.2 This outcome at four weeks should be either QUIT, NOT QUIT or LTF – LOST TO FOLLOW UP. **Data quality:** There should be a strong emphasis on collecting and reporting gold standard data and should be attempted for all quit attempts. Gold standard data includes a quit rate of above 50%, Carbon monoxide monitoring above 85%, lost to follow up rate of 15% or below, and above 90% of all clients ethnicity, occupations and the medication used.

10.3 The pharmacy will complete PharmOuctomes for each client who is seen from weeks 5-8 and 9-12 weeks.

10.4 It is the Pharmacy responsibility to inform the client that at the end of the 12 week period they will have to purchase any subsequent NRT products.

10.5 The Pharmacy will ensure that they provide CO monitoring to all clients and it is the Pharmacy's responsibility to purchase subsequent CO monitor tubes and D pieces once the starter kit has been used. The Pharmacy is responsible for the disposal of clinical waste and infection control measures in line with their company policy.

10.6 The pharmacy reviews its standard operating procedures and the referral pathways for the service. The pharmacy will maintain links with local smoking cessation services to ensure that referral pathways are maintained.

10.7 The pharmacy can demonstrate that pharmacists and staff involved in the provision of the service have undertaken CPD relevant to this service and locally organised training provided by accredited trainers as agreed with the Commissioner including an annual Level 2 training update.

10.8 The pharmacy participates in an annual organised audit of service provision and quality which will be completed by Cambridgeshire County Council/JCU in partnership with the Local Pharmaceutical Committee.

10.9 The pharmacy co-operates with any locally agreed assessment of service user experience.

10.10 The pharmacy should inform the Cambridgeshire County Council and the JCU if they are no longer able to participate in the scheme due to movement of trained staff or if they no longer wish to participate in the

scheme. A minimum of one month's notice period should be given to the JCU should the Pharmacy wish to terminate or temporarily put the service on hold.

10.11 When the client has completed their programme of support through the community pharmacy scheme and wishes to continue to receive support, the Pharmacy can offer further support or refer the client back to the CAMQUIT service who sit with the local Lifestyles Service.

11. Data Returns and Remuneration

11.1 A finite amount of funding is available for community pharmacy provision of a smoking cessation service. Cambridgeshire County Council will regularly review provision of the service and funding available.

11.2 Smoking cessation data should be updated on the PharmOutcomes system each month and is based on the month that the client's quit date has been set.

Please ensure that all outcomes are complete before returning data. If it has not been possible to see the client for 4-week follow-up within the month please send in the completed form when the client has been seen and the outcome is known.

11.3 The fee structure for community pharmacy participation in the scheme will be:

a) **Payment element one:** A fee of £15 will be paid to the pharmacy for return of data on clients entering the scheme and setting a quit date*

b) **Payment element two:** An additional fee of £15 will be paid to the pharmacy per successful quitter at 4 week follow up

c) **Payment element three:** An additional payment of £5 will be made to the pharmacy for each quit attempt whose 4 week outcome data is submitted and meets **all** 'gold standard' data requirements. This means that it must be a CO verified quit with the following data recorded; ethnicity, socioeconomic status and pharmacotherapy used.

d) **Payment element four:** Pharmacies will be paid £2.50p for each NRT product dispensed on receipt of voucher.

- Pharmacies will be reimbursed for NRT supplied at drug tariff cost, set for the financial year as per the BNF values on 1st April 2019. Tariff costs will be reviewed and renewed on an annual basis

*Pharmacies are liable for VAT.

Payments for element two-four (data regarding a client's quit attempt and prescription) will be processed once Public Health Commissioning Unit receive monitoring data from the Pharmoutcomes. .

11.5 Reimbursement: The estimated cost of supply of Nicotine Replacement Therapy linked to this programme is based on the Drug Tariff set for the financial year as per the BNF values on 1st April 2019. Tariff costs will be reviewed and renewed on an annual basis

Appendix 1- Smoking Cessation voucher <u>NRT VOUCHER FOR COMMUNITY PHARMACY SUPPLY</u>

CLIENT: Please take this form to a participating pharmacy (see below) within TWO WEEKS of initial consultation to obtain your NRT product and complete the prescription charge/exemption information overleaf.
SMOKING ADVISOR: Please complete fully and void products not required.

Client name:		**Advisor name (please print):**	**OFFICE USE ONLY** Date Received
Client address: **Postcode:**		**Advisor signature:**	
Prescription exemption code (if applicable)		**Contact number:** **Date:**	

Void products <u>NOT</u> to be prescribed	**Product**	**Dose**	**2 weeks supply**	**State prescription charge paid if applicable**	**Brand (to be completed by pharmacy staff)**
☐	Patch 16 hour	25mg ☐15mg ☐ 10mg ☐	14 ☐		
☐	Patch 24 hour	21mg ☐14mg ☐ 7mg ☐	14 ☐		
☐	Gum	4mg ☐ 2mg ☐	2 x 105 ☐ 2 x 96 ☐		
☐	Mini Lozenge	4mg ☐ 1.5mg☐	4 x 60 ☐		
☐	Cools Lozenge	4mg ☐ 2mg ☐	3 x 80 ☐		
☐	Lozenge	4mg ☐ 2mg ☐	4 x 96 ☐ 2 x 96 ☐		
☐	Inhalator	15mg☐	3 x 36 ☐ 4 x 20 ☐		
☐	Mouth spray	1mg ☐	3 x duo packs ☐		
☐	Oral Strips	2.5mg ☐	4 x 60 ☐		

☐	Micro tablet	2mg ☐	5 x 105 ☐		
☐	Nasal Spray	0.5mg ☐	5 units ☐		

Note to pharmacist from advisor	

PHARMACY STAFF: Please supply NRT as directed above, add the brand of product/s dispensed, complete the information below and return the voucher for payment.

Pharmacist signature:	**Date:**
Pharmacy name/address/stamp:	**Please return completed forms to:** Camquit Cambridgeshire County Council Box No CC1318 Castle Court Cambridge CB3 0AP

I confirm that the NRT requested above was supplied to the above client.

PRESCRIPTION CHARGE/EXEMPTION INFORMATION

To the client: Patients who don't have to pay must fill in parts 1 and 3. Those who pay must fill in parts 2 and 3.

Part 1	The patient doesn't have to pay because he/she:
A ❒	Is under 16 years of age
B ❒	Is 18 years of age and in full-time education
C ❒	Is 60 years of age or over
D ❒	Has a valid maternity exemption certificate
E ❒	Has a valid medical exemption certificate
F ❒	Has a valid prescription prepayment certificate
G ❒	Has a War Pension exemption certificate
L ❒	Is named on a current HC2 charges certificate
H ❒	Gets Income Support (IS)*
K ❒	Gets Income-based Jobseeker's Allowance (JSA (IB))*
M ❒	Is entitled to, or named on, a valid NHS Tax Credit Exemption Certificate*
S ❒	Has a partner who gets Pension Credit guarantee credit (PCGC)*

* If benefit or tax credit is paid to your partner or someone else for you, give their details here:

Declaration For patients who do not have to pay	I declare that the information I have given on this form is correct and complete. I understand that if it is not, appropriate action may be taken. I confirm proper entitlement to exemption. To enable the NHS to check I have a valid exemption and to prevent and detect fraud and incorrectness, I consent to the disclosure of relevant information from this form to and by the NHS Business Services Authority, the NHS Counter Fraud and Security Management Service, the Department for Work and Pensions and Local Authorities. **Now sign and fill in Part 3**
Part 2	I have paid £ **Now sign and fill in Part 3**
Part 3	Cross ONE box I am the patient ❒ patient's representative ❒
Sign here:	Date / /

Appendix 2-Smoking Cessation Service Data Quality Information Sheet

Definitions

Smoked product
Any product that contains tobacco and produces smoke is a smoked product, including cigarettes (hand-rolled or tailor-made), cigars and pipes. Pipes include shisha, hookah, narghile and hubble-bubble pipes.

Smokeless product
There is evidence to show that the use of smokeless tobacco products (e.g. chewing tobacco, paan, khat) can have negative health effects, including oral cancers. There is some evidence to suggest that behavioural support can be effective.

Quit date
Date a smoker plans to stop smoking altogether with support from a stop smoking adviser as part of an NHS-assisted quit attempt.

Self-reported four-week quitter
A treated smoker whose quit status at four weeks from their quit date (or within 25 to 42 days of the quit date) has been assessed either face-to-face or by telephone, text, or email

Carbon monoxide-verified four-week quitter
A treated smoker whose Co reading is assessed 28 days from their quit date (-3 or + 14 days) and whose Co reading is less than 10ppm. The -3 or +14 day rule allows for cases where it is impossible to carry out a face-to-face follow-up at the normal four-week point (although in most cases it is expected that follow-up will be carried out at four weeks from the quit date). This means that follow-up must occur 25 to 42 days from the quit date (Russell Standard). Co-verification should be conducted face-to-face and carried out for at least 85% of self-reported four-week quitters.

Not Quit at four weeks
A treated smoker who has set a date to stop smoking and when monitored within 25 to 42 days of the quit date has smoked within the past two weeks. This outcome can be assessed by self-report or confirmed with a Carbon monoxide verification test.

Lost to follow-up (LTFU)

A treated smoker who cannot be contacted either face to face or via telephone, email, letter or text following three attempts to contact at different times of day, at four weeks from their quit date (or within 25 to 42 days of the quit date). The four-week outcome for this client is unknown and should therefore be recorded as LTFU on the monitoring form. NHS Cambridgeshire LES agreements do not pay for patients who are lost to follow up.

Not completed data
A client who has received an intervention and set a quit date but there is missing data or no clear outcome at four weeks.

Target
This is the providers' target of the total number of people who have set a date to stop smoking and have stopped (quit) when monitored at the four week stage.

Performance %
This is the total % of achievement against the target set, e.g. target= 50 quitters, current quitter total 25 would be 50% of target.

Success rate
Is the total number of people who have set a date to stop smoking and have stopped smoking at four weeks: set quit date total – quit. E.g. 30 people set a quit date and 15 were quit at four weeks would be 50% success rate.

CO verified %
This is the total % of people who have had a carbon monoxide test recorded out of the total number of people who have been recorded at Quit when monitored at the four week stage e.g. total number of people who were recorded as quit 20 and of these people 5 had a carbon monoxide test completed= 25% co verified.

Explanations

Why Do We Record Occupation?

Reducing health inequalities is a public health priority. Routine and Manual (R&M) workers have higher smoking prevalence than general population and it is important that we target priority population groups, as well as the general population, to contribute toward a reduction in health inequalities.

Recording occupation also helps service mapping and the development and delivery of the Cambridgeshire service in the future, as well as actually helping you as an advisor to understand and guide your client appropriately.

Please note:

If you are recording 'occupation' on a GP surgery template please first try to type in the generic name of the persons job i.e. chef or cleaner, and this should bring up a shorter picking list to choose from. Please try and avoid leaving it blank or unable to code.

1. Unemployed - A client is classified as long term unemployed if they have currently been unemployed for one year or more. If unemployed for less than a year last known occupation should be used for classification
2. Home Carer - i.e. looking after children, family or home
3. Self Employed - If a client is self-employed please use the flowchart below to determine classification
4. Unable to Code - If you are still unable to establish this, please record as unable to code

Managerial and Professional Occupations:	**Intermediate Occupations:**	**Routine and Manual Occupations:**
Academic	Administrator	Bartender
Accountant	Bank Clerk	Fitter
Artist	Call centre agent	Caretaker
Athlete/sportsperson	Clerical worker	Catering assistant
Civil/mechanical engineer	Electrician	Cleaner
Consultant	Gardener	Farm worker
	Inspector	HGV driver

Why Record Ethnicity?

Recording ethnicity is important as some black and minority ethnic (BME) communities have high smoking prevalence rates compared with the general population. Recording ethnicity also helps service mapping and the development and delivery of the Cambridgeshire service in the future, as well as actually helping you as an advisor to understand and guide your client appropriately.

Why Record Pharmacotherapy?

So that we can know which pharmacotherapies are most commonly used and which are the most effective in helping people stop smoking. It is also an important indicator of data quality and we request that you do record this and that it is not added as free text.

Why Record Carbon Monoxide Levels?

CO verification rates are an important marker of data quality, and should be carried out on all adult smokers to provide a pre-quit and post quit level. Recording carbon monoxide levels is an excellent way to motivate people during a quit attempt. The Government have requested that service achieve at least 85% CO recording for four week quitters. Please contact the service if you need support with your Carbon Monoxide Monitor.

Appendix 3- Prescribing Guidance for Smoking Cessation Treatment Programmes

CAMBRIDGESHIRE & PETERBOROUGH STOP SMOKING SERVICE'S

Stop Smoking Pharmacological Products Guidance

This guidance is for use by

Cambridgeshire Stop Smoking Service (CAMQUIT), Healthy Peterborough Stop smoking Service, GP Practices, Pharmacies participating in the Community Pharmacy Stop Smoking Service and Cessation advisors who have received specialist training through the Cambridgeshire or Peterborough services (such as those based within the School Nursing teams -Cambridgeshire only)**.**

Purpose

The purpose of the Stop Smoking Pharmacological Products Guidance is to ensure consistency and cost effectiveness across Cambridgeshire and Peterborough in the approach taken to advising and supporting people who wish to stop smoking, improving the clinical and cost effectiveness of prescribed medicines and reducing medicines wastage.

Summary

Helping an individual to stop smoking requires understanding their lifestyle and personal preferences. It is therefore important to provide a choice of interventions, accompanied by supporting information regarding relative chances of success, possible side effects and ease of access.

Clients will be seen initially at their GP surgery (if there is a level 2 stop smoking advisor), Cambridgeshire or Peterborough Stop Smoking Services, the Community Pharmacy, through the school nursing team or community based level 2 smoking cessation advisor where they will be given behavioural support and advice regarding stopping smoking.

Clients should be assessed carefully with regard to their motivation to quit smoking using a nicotine dependence assessment tool and assessment of readiness to quit tool. If their level of motivation to quit is not sufficiently high then the client should be given appropriate information and advised to make a further appointment when they feel they may be ready to make a serious attempt to quit or should be followed up by a stop smoking advisor.
If the individual is ready to make a serious attempt to quit smoking then the following approach should be taken:
A full discussion should take place and should include information on the standard treatment 12 week programme, setting a quit date and medication options and ongoing support. This may include the use of pharmacotherapies that are available to the client to help them quit smoking using the protocols below.

Pharmacotherapy options

CAUTION:
Clinicians should be aware of the possible emergence of significant depressive symptoms in patients undergoing a stop smoking attempt with or without pharmacotherapy, and should advise patients accordingly.

The MHRA has recommended that varenicline should be discontinued immediately if agitation, depressed mood, suicidal thoughts/behaviour or other changes in behaviour are observed.

If the decision is taken that pharmacotherapy is necessary, then the initial treatment option should be chosen by the patient based on information provided by the stop smoking advisor through their assessments and consultations. This should consist of a product that meets the needs and lifestyle of the client in order to increase adherence to the programme and to increase long term success. This should be used in conjunction with formal counselling, advice and support from the stop smoking advisor.

All smokers should be given the optimum chance of success in any given quit attempt. Licenced pharmacotherapy, currently nicotine replacement therapy (NRT), Champix (varenicline) and Zyban (bupropion) should all be made widely available in combination with intensive behavioural support as equal first-line treatment (where clinically appropriate)[1]

First Line Therapy choices:

a) NRT product + Behavioural counselling

b) A combination of two NRT products + Behavioural counselling (e.g. a baseline patch the strength of which is suitable to the level of cigarette usage and an additional product such as lozenges, gum, inhalator, spray, thins or microtabs for occasional use).

c) Varenicline (Champix) + Behavioural counselling

d) Bupropion (Zyban) + Behavioural counselling

The following should be noted carefully:

A combination of NRT products (combination therapy) has been shown to have an advantage over using just one product. It is also considered cost-effective. Stop smoking service providers should therefore routinely offer clients combination therapy whenever appropriate.

Combinations of NRT with Varenicline (Champix®) or Bupropion (Zyban®) should **NOT** be offered. There is no evidence available for the use of NRT in combination with Varenicline or Bupropion Hydrochloride.

Varenicline and Bupropion are only available on prescription and it is at the discretion of the individual prescriber whether a request to prescribe is agreed to.

Combining behavioural support with pharmacotherapy increases a smoker's chances of successfully quitting by up to 35%[2].

Stop Smoking medications approved by NICE[3] are NRT, Varenicline (Champix®) and Bupropion (Zyban®).

The effectiveness of pharmacotherapy, using individual behavioural support gives four-week quit rates of[4]:

- No medication – 22%
- Mono NRT – 37%
- Combination NRT – 50%
- Bupropion (Zyban®)– 39%
- Varenicline (Champix®) – 52%

Supporting information regarding the relative effectiveness of each intervention type should be given. The Department of Health have smoking cessation booklets free of charge, patient information leaflets through the website electronic medicines compendium www.medicines.org.uk.

[1] http://www.ncsct.co.uk/usr/pub/LSSS_service_delivery_guidance.pdf

[2] Stead LF, Perera R, Bullen C, Mant D and Lancaster T (2008) 'Nicotine replacement therapy for smoking cessation.' Cochrane Database of Systematic Reviews

[3] https://www.nice.org.uk/guidance/PH10/chapter/4-Recommendations#pharmocotherapies-and-other-treatment

[4] http://www.ncsct.co.uk/usr/pub/LSSS_service_delivery_guidance.pdf

The Cambridgeshire Stop Smoking Service CAMQUIT also have patient information leaflets available via their website: www.camquit.nhs.uk or via **01480 278 667**.
Information about Peterborough's' service is available 0800 376 5655 and via the website: https://www.healthypeterborough.org.uk click on the Stop Smoking tab.

All pharmacotherapies should remain available for the period recommended in the product SPC and access to supplies should be made simple and easy.

Prescribing duration

Prescriptions for supplies of NRT, Varenicline (Champix®) or Bupropion (Zyban®) should not exceed a maximum of 4 weeks. It is recommended that prescription requests are processed every one-two weeks for the course of treatment (up to twelve weeks from the quit date). This duration allows for re-assessment of product suitability & correct use and quit attempt progress up to the 4 week monitoring and reporting stage. It is recommended that all prescriptions for smoking cessation medications are recorded as 'acute' and are ***not*** added to the clients repeat prescription list.

Pharmacotherapies should be available for more than one treatment episode. **There is no definitive period between quit attempts**, and provided the client remains motivated they should be given a new course of treatment in line with a new treatment episode. This includes intervention with Prescription Only Medications such as Varenicline (Champix®) or Bupropion (Zyban®).

If a client relapses and does not wish to begin a new treatment episode, no further prescriptions should be given until such time they are motivated to quit again.

Smoking cessation specification extract:

<table>
<tr><th></th><th colspan="3">SPECIFICATION</th></tr>
<tr><td>1a</td><td colspan="3">Initial assessment- Brief advice (5 minutes)
Ask and record smoking status
Assessment of person's readiness to make quit attempt and provide referral to cessation service</td></tr>
<tr><td>2a</td><td colspan="3">Initial consultation (15-30 minutes)
Set quit date
Supply 1-2 weeks NRT/Zyban/Champix
Complete monitoring form
Carbon monoxide (CO) test validation
Complete the patient records notes</td></tr>
<tr><td>3a</td><td>Follow up (10 minutes)
Re-assess cessation progress and smoking status
Supply 1-2 weeks NRT/Zyban/Champix
Complete monitoring form
Carbon monoxide (CO) test validation
Complete the patient records notes</td><td>3b</td><td>Follow up (10 minutes)
Re-assess cessation progress and smoking status
Supply 2 weeks NRT/Zyban/Champix
Complete monitoring form
Carbon monoxide (CO) test validation
Complete the patient records notes</td></tr>
<tr><td>4a</td><td>4 week follow up (10 minutes)</td><td>4b</td><td>If client has NOT QUIT</td></tr>
</table>

	If client has QUIT 5-8 weeks after ***QUIT*** date (5-10 minutes) ▪ Re-assess cessation progress and smoking status ▪ **Supply 4 weeks NRT/Zyban/Champix** ▪ Complete monitoring form ▪ Carbon monoxide (CO) test validation ▪ Complete the patient records notes		5-8 weeks after QUIT date (5-10 minutes) ▪ Re-assessment motivation to make a quit attempt ▪ Consider re- setting the quit date and beginning the programme again at stage 1
5	9-12 weeks after ***QUIT*** date (5-10 minutes) ▪ Further **supply of NRT for 4 weeks** if appropriate CO test (optional) ▪ Complete patient notes		

Dispensing procedure

FP10 fees should be collected for supply of medication if patient exemption does not apply.

GP practice based smoking cessation service

1. GP Practice based stop smoking services should ensure they have an established practice procedure for issuing stop smoking pharmacotherapy's in line with Cambridgeshire's & Peterborough's guidance.

CAMQUIT & PETERBOROUGH Stop Smoking Service Advisors who are not based within a GP surgery - NRT

1. Should complete a prescription request form for NRT and send to the clients GP surgery. No patient appointment is required unless the practice procedure states otherwise or the client presents contraindications to NRT.
2. Alternatively a nicotine replacement therapy voucher can also be given to the client to be processed by the local Pharmacist as part of the Pharmacy voucher scheme contract (CAMQUIT ONLY)

CAMQUIT & PETERBOROUGH Stop Smoking Service Advisors who are not based within a GP surgery - Zyban or Champix

1. Clients who are a medically suitable candidate for Varenicline or Bupropion should be referred for an appointment with their GP with their completed CAMQUIT Champix or Zyban prescription request form.

Community based advisors who are not commissioned by Peterborough City Council, Cambridgeshire Community Services or Cambridgeshire County Council

1. Should contact their link advisor within the specialist services once their client is ready to access treatment medications. The link advisor will be responsible for supporting the advisor and client with following the necessary prescribing procedures.

Pharmacy based stop smoking service

1. Should ensure that there is an established procedure for issuing stop smoking NRT pharmacotherapy choices and that it is the Pharmacists responsibility to issue the medication in line with the Cambridgeshire and Peterborough's Stop Smoking Service guidance.
2. Clients who wish to use Varenicline or Bupropion should be referred for an appointment with their GP but can continue to use the pharmacy service for behavioural support alone.

CCS School Nurse smoking cessation advisors

1. Should complete a prescription request form for NRT and send to the clients GP surgery. No patient appointment is required unless the practice procedure states otherwise or the client presents contraindications to NRT.
2. Alternatively a nicotine replacement therapy voucher can also be given to the client to be processed by the local Pharmacist as part of the Pharmacy voucher scheme contract.

Stopping treatment

All products (NRT, Champix and Zyban) should be used as indicated in the SPC and if the client has successfully quit at the four week stage they should continue to use the product for the full treatment course as indicated in the SPC (usually up to12 weeks). At the end of the treatment course the medication use should cease and the patient should be informed about self-care, if they require NRT in the future this can be purchased from local pharmacies and supermarkets.
All products should be used as part of a smoking cessation standard treatment programme along with behavioural support from an approved smoking cessation advisor.

Treatment should be stopped immediately and the clients quit attempt reassessed if:

- The client reports a suspected adverse reaction after authorisation of the medicinal product. The risk/benefit balance of the product should be monitored. Healthcare professionals are asked to report any suspected adverse reaction via the Yellow Card Scheme, www.mhra/gov.uk/yellowcard.
- The client is recorded as 'not quit' or 'lost to follow up' at the four week stage. Continued treatment should cease until a full re-assessment and new quit date has been established.
- The client under 18 years old is not deemed 'Fraser competent' to use the treatment appropriately.
- The client develops a new medical condition/illness which is not associated with nicotine withdrawal. The GP/Health professional should then make assess the risk/benefit of continued use of the medication.
- The treatment choice is not suitable for the client and a new product is issued.
- The client chooses to use an electronic cigarette to stop smoking.

Smoking Cessation in Pregnancy & Breastfeeding

Special considerations
Smoking during pregnancy causes serious complications both during the pregnancy and afterwards and is a major cause of infant mortality and Sudden Infant Death Syndrome.
The use of nicotine replacement therapy in pregnancy is preferable to the continuation of smoking, but should be used only if smoking cessation without nicotine replacement fails. Advice regarding the risks and benefits of using NRT in pregnancy should be given by a trained adviser who has attended the specialist smoking and pregnancy training.

Access to NRT during pregnancy should be available on the recommendation of an adviser who has completed the Smoking in Pregnancy training. Pregnant smokers with an obstetric/medical condition and/or taking regular medication should be seen by a health professional or referred to the specialist service.

Medication choices

- Intermittent products are preferable to patches but avoid liquorice-flavoured nicotine products. Patches should be made available to women who cannot tolerate oral NRT products, if the patient is experiencing pregnancy-related nausea and vomiting. If patches are used, they should be removed before bed.

- Combination Therapy can be made available for heavily dependent smokers when considered to be clinically appropriate.

- Breast feeding is not a contraindication to the use of NRT. The use of intermittent NRT products is preferred in order to allow maximum time between NRT use and breastfeeding.

- Varenicline and Bupropion Hydrochloride are contraindicated for pregnant and breast feeding women.

Prescribing procedure

GP practice based smoking cessation service

1. GP Practice based stop smoking services should ensure they have an established practice procedure for issuing stop smoking pharmacotherapy's in line with Cambridgeshire's & Peterborough's guidance.

CAMQUIT & PETERBOROUGH advisors who are not based within a GP surgery who want to use NRT

1. Should complete a prescription request form for NRT and send to the clients GP surgery. No patient appointment is required unless the practice procedure states otherwise or the client presents contraindications to NRT.
2. Alternatively, for (CAMQUIT ONLY) a nicotine replacement therapy voucher can also be given to the client to be processed by the local Pharmacist as part of the Pharmacy voucher scheme contract, but it is the responsibility of the Pharmacist to provide the intervention and issue the NRT. Under the terms of the Public Health Contract all pharmacists in Cambridgeshire who have registered to deliver smoking cessation interventions ideally must have had CAMQUIT specialist smoking and pregnancy training prior to providing smoking cessation interventions for pregnant women.

   The Pharmacy should ensure that there is an established procedure for issuing stop smoking NRT pharmacotherapy choices and that it is the Pharmacists responsibility to issue the medication in line with the Cambridgeshire and Peterborough's Stop Smoking Service guidance.

   The GP or clinician overseeing the pregnancy should be informed.

Pharmacy based stop smoking service

1. Pregnant women can be provided with NRT directly through a community pharmacy without consultation with their GP but it is the responsibility of the Pharmacist to provide the intervention and issue the NRT. Under the terms of the Public Health Contract all pharmacists in Cambridgeshire who have registered to deliver smoking cessation interventions ideally must have had CAMQUIT specialist smoking and pregnancy training prior to providing smoking cessation interventions for pregnant women.

   The Pharmacy should ensure that there is an established procedure for issuing stop smoking NRT pharmacotherapy choices and that it is the Pharmacists responsibility to issue the medication in line with the Cambridgeshire and Peterborough's Stop Smoking Service guidance.

   The GP or clinician overseeing the pregnancy should be informed.

Smoking Cessation for clients with Mental Health illness

Due to higher levels of nicotine dependence, the amount of NRT required by smokers with mental illness is likely to be higher than the rest of the population.

Licensed nicotine products contain lower levels of nicotine than tobacco and the way these products deliver nicotine makes them less addictive than smoking. NRT does not interact with any mental health medicines or affect the blood levels of medication, ***though smoking and stopping smoking can affect such levels.***

It is safe to give NRT to smokers with a mental illness, even those who receive high doses of psychotropic medication and those who continue to smoke.

In a minority of cases, smoking cessation, with or without pharmacotherapy, is associated with an exacerbation of depression. Stop smoking practitioners should be aware of the possible emergence of depression in clients undertaking a quit attempt.

Effect of smoking cessation on medication blood levels

Tobacco smoke speeds up the metabolism of some antipsychotic medications, as well as some antidepressants and benzodiazepines, by inducing certain liver enzymes (CYP4501A2 isoenzyme). This effect is not caused by nicotine but is secondary to the polycyclic aromatic hydrocarbons from the tar in tobacco smoke.

A consequence of speeding up the metabolism of some medicines is that smokers need higher doses of some psychotropic medicines compared to non-smokers. Blood levels of medication will be affected by many things such as age, gender and how well they adhere to their prescribed treatment. Stopping smoking can result in an increase in blood levels of some medicines (see chart below) these are likely to increase within seven days of quitting. Because this could potentially led to toxicity, doses of affected psychotropic medicines **may need to be reduced by 25–50% once someone stops smoking.**

Blood levels, clinical symptoms and any changes in the frequency and severity of side effects all need to be closely monitored when cigarette consumption is reduced or stopped, but also for a few weeks after patients are discharged, as they may start smoking again. Blood levels of clozapine may still be altered for up to six months after stopping smoking.

Therefore, dose reduction needs to be considered if a patient stops smoking.

This NHS Specialist Pharmacy Service Medicines Q&A (Appendix 2) summarises those drug interactions with cigarette smoking that are considered to be most clinically important.

Young People

Special considerations

- NRT is licensed for use in young people aged 12 and above but medical advice should be obtained if it is necessary to use beyond 12 weeks or if the client has medical conditions which are listed as contraindications for NRT.
- For people aged 13-16 year olds please assess and complete a Fraser competency form so that young people under the age of 16 can consent to medical treatment if they have sufficient maturity and judgement to enable them fully to understand what is proposed.
- For anyone under the age of 12 years please seek the child's parental consent or refer the smoker back to their GP or Pharmacist.
- Dispensing procedure is the same as Dispensing procedures on page 4.
- Zyban and Champix are contraindicated for under 18 year olds.

Electronic Cigarettes

Electronic cigarettes are not currently licensed for smoking cessation and as with other unlicensed nicotine containing products, the stop smoking service cannot provide or prescribe them.

However clients who register with the stop smoking service should be given information on licensed products such as Nicotine replacement therapy, Zyban and Champix and also the non-licensed products such as electronic cigarette so that they can make an informed decision about their stop smoking plan.

In 2015 Public Health England said *'E-cigarettes are significantly less harmful to health than tobacco and have the potential to help smokers quit smoking'.*

For further information about electronic cigarettes

1) http://www.ncsct.co.uk/usr/pub/e-cigarette_briefing.pdf
2) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/680964/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf
3) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf

Background information on the local smoking cessation services

In Peterborough the Public Health Delivery team transferred from NHS Peterborough to Peterborough City Council in October 2012 under the People and Communities Directorate where the smoking services was delivered in conjunction with other public health priorities including, lifestyle programmes, health checks and health improvement accredited training. On April 1 2017, the Public Health stop smoking team was outsourced to Solutions for Health who will deliver an integrated lifestyle service within Peterborough.

The Public Health Directorate transferred from NHS Cambridgeshire to Cambridgeshire County Council in April 2013 as a result of the Health and Social Act 2012.

The Public Health Directorate manages contracts with health and social care providers to deliver smoking cessation services and this policy aims to provide good practice guidance when prescribing smoking cessation treatment medications. The CAMQUIT Stop Smoking Service was transferred to Everyone Health who deliver the integrated lifestyle service within Cambridgeshire on July 1st 2017.

Local stop smoking services follow The National Centre for Smoking Cessation and Training (NCSCT) Standard Treatment Programme which sets out a standard method for supporting an individual to stop smoking involving an initial assessment and continued motivational interviewing sessions whereby the advisor forms an understanding about the clients' health, lifestyle, circumstances and preferences. It is therefore important to provide a choice of interventions, accompanied by supporting information regarding relative chances of success, possible side effects and ease of access so that the client can make an informed choice about their quit attempt.

APPENDIX 4

PHARMACOTHERAPIES AVAILABLE

Please refer to BNF or each product SPC for full prescribing information including contraindications cautions and drug interactions:

https://bnf.nice.org.uk/

http://emc.medicines.org.uk

Nicotine Replacement Therapy (NRT)

NRT can be prescribed as single or combination therapy

Patches

Nicorette Invisi (16 hour) 25mg, 15mg, 10mg

Nicotinell TTS(24 hour) 21mg, 14mg, 7mg

Niquitin & Niquitin Clear (24 hour) 21mg, 14mg, 7mg

Lozenges

Nicorette Cools 2mg, 4mg,

Nicotinell 1mg, 2mg

Niquitin CQ 2mg, 4mg

Niquitin Minis 4mg, 1.5mg

Nicorette Microtabs

Nicorette 2mg

Chewing Gum

Nicorette Gum 2mg, 4mg, 6mg

Nicotinell Gum 2mg, 4mg

Niquitin CQ Gum 2mg, 4mg

Inhalator

Nicorette 15mg

Nasal Spray

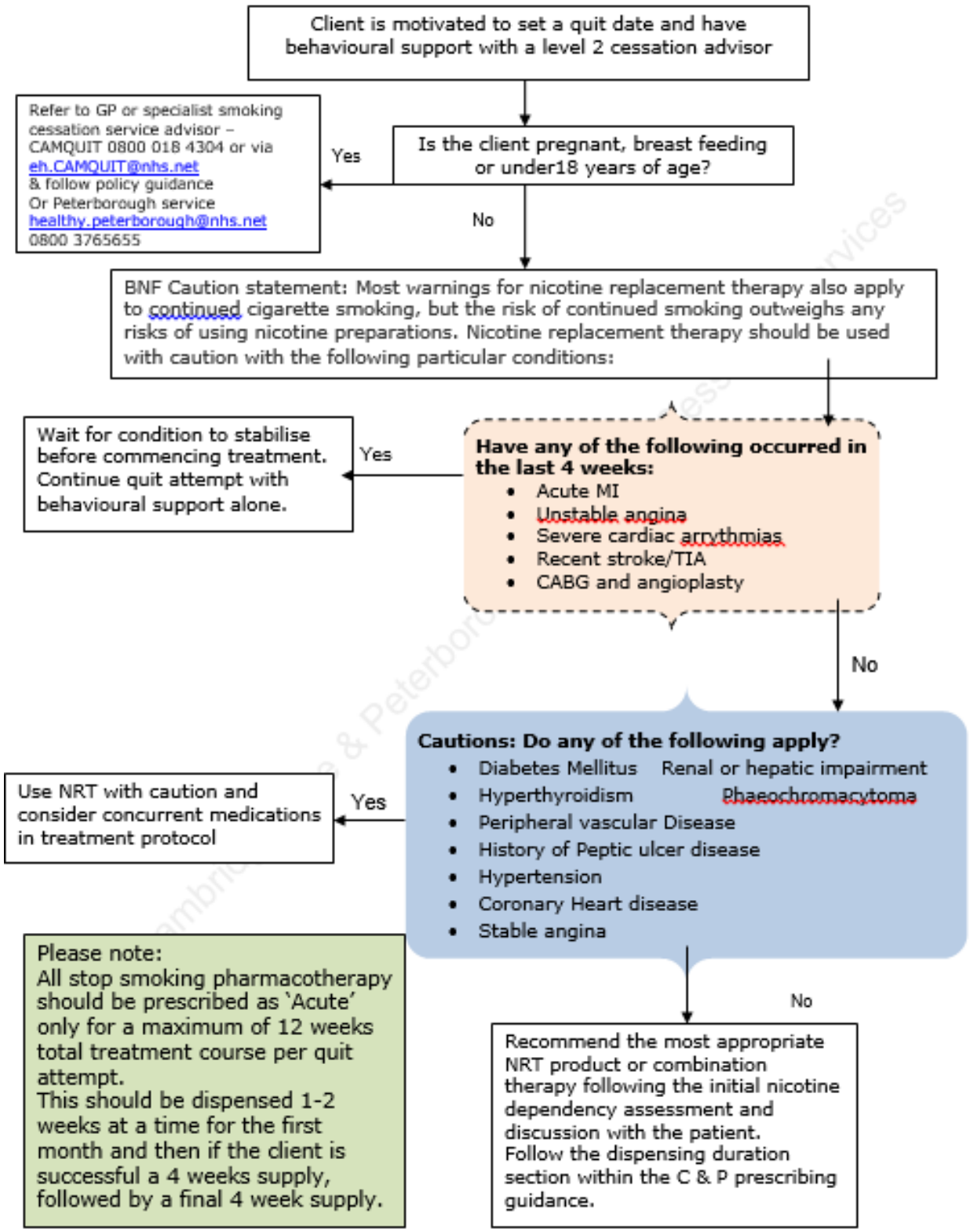
Nicorette 10ml (0.5mg per dose)

Mouth Spray

Nicorette Quickmist 1mg per spray

Any new NRT product which is licensed as GSL

Nicotine replacement therapy for Smoking Cessation 2018-19



Champix (Varenicline®)

Starter Pack: 0.5mg & 1mg oral tablets
Maintenance: 1mg tablets, 0.5mg oral tablets

Dose: start 1–2 weeks before target stop date.
Initially 500 micrograms once daily for 3 days,
Increased to 500 micrograms twice daily for 4 days,
Then 1 mg twice daily for 11 weeks (reduce to 500 micrograms twice daily if not tolerated);

Contraindications:
Pregnancy or breastfeeding – not licensed
Patients under 18 years of age – not licensed
End stage renal disease – not licensed

Cautions:

- Patients with a history of psychiatric illness should be monitored closely when taking Champix
- Patients should be advised to discontinue treatment and seek medical advice if they develop depressed mood or changes in behaviour, agitation or suicidal thoughts
- Patients with renal disease can take a reduced dose

The Medicines and Healthcare products Regulatory Authority (MHRA) issues the following advice

Patients and their family or caregivers should be made aware of the possibility that trying to stop smoking might cause symptoms of depression

- Patients who are taking varenicline who develop suicidal thoughts or behaviour should stop their treatment and contact their doctor immediately
- Varenicline should be discontinued immediately if agitation, depressed mood, or changes in behaviour are observed that are of concern for the doctor, patient, family, or caregiver
- Patients with serious psychiatric illness did not participate in the premarketing studies of varenicline, and the safety and efficacy of varenicline in such patients has not been established. Care should be taken when prescribing varenicline to patients who have a history of psychiatric illness

Varenicline and Cardiovascular events

- Smoking is a major risk factor for cardiovascular disease;
- A recent review indicated that it may be worth investigating the link between cardiovascular events and Varenicline further, but currently there is little reason to avoid this medication on these grounds. This view is in line with European Medicines Agency that confirmed a positive benefit-risk balance Varenicline and concluded that its benefits as a smoking cessation medicine outweigh any slight increase in cardiovascular events. People with Cardiovascular disease who taken Varenicline should report to their doctor any new or worsening symptoms of cardiovascular disease. For example: shortness of breath or trouble breathing; new or worsening chest pain; new or worse pain in the legs when walking.

Interactions:

- Champix has no clinically significant drug interactions.

GP Prescribing protocol - Varenicline for Smoking Cessation

Do not use Varenicline with those who are:
- Under 18 years old
- Pregnant and/or breastfeeding
- End stage renal disease

Clients using the local smoking cessation services and wishing to use Varenicline will be referred to their own GP with an accompanying letter/prescription request form. The GP will make a clinical assessment of the client to establish their suitability for Varenicline. It remains the clinical decision of each individual GP as to whether a prescription for Varenicline is issued. **Decision to prescribe?**

Caution: do any of the following apply?
- Client has epilepsy
- Client has a psychiatric illness
- Client has heart disease
- Client has diabetes
- Client has COPD
- Client has renal disease

Yes

Is the condition stable and regularly monitored?

No

Refer client back to the smoking cessation service/advisor for further advice and assessment for NRT to be considered as part of the treatment programme.

Yes

No

A quit date is set for two weeks time and a follow up appointment should be arranged with the stop smoking advisor.

Prescribe Varenicline for a maximum 12 week course at 2 weekly intervals in conjunction with behavioural support and regular monitoring sessions with a smoking cessation advisor.

≥ 30 ml/min estimated creatinine clearance (no renal impairment, mild and moderate renal impairment)

Day 1 – 3	0.5mg	Once daily
Day 4 – 7	0.5mg	Twice daily (8 hours between each dose)
Day 8 to end of treatment (12 wks)	1.0mg	Twice daily (8 hours between each dose)

Monitor progress and reassess for any adverse events every 2 -4 weeks for the 12 week treatment duration

Please note: If full dose cannot be tolerated Lower dose to 0.5mg b.d. either temporarily or permanently depending on response.

Please note: Ensure prescription is 'Acute' only and consider dose tapering on completion of 12-week course

Reviewed Feb 2018

Zyban (Bupropion®)

150mg tablets

Dose:
Start 1–2 weeks before target stop date, initially 150 mg daily for 6 days
then 150 mg twice daily (max. single dose 150 mg, max. daily dose 300 mg; minimum 8 hours between doses);

Period of treatment 7–9 weeks; discontinue if abstinence not achieved at 7 weeks;
Consider max. 150 mg daily in patients with risk factors for seizures;

ELDERLY max. 150 mg daily

Contraindications:

- History of seizures or eating disorders, bipolar disorder, CNS tumour, patients experiencing abrupt withdrawal of alcohol or benzodiazepines, factors which lower the threshold for seizure such as antimalarials and antidepressants etc., sedating antihistamines, diabetes, severe hepatic cirrhosis
- Pregnancy or breastfeeding
- Patients under 18 years of age

Cautions:

- Mild to moderate renal impairment
- Diabetes
- Monitor BP before and during treatment, especially in patients with pre-existing hypertension, monitor BP weekly
- History of psychiatric illness or head trauma
- Elderly maximum dose 150mg

Interactions:
In patients receiving medicinal products known to lower the seizure threshold, Zyban must only be used if there is a compelling clinical justification for which the potential medical benefit of smoking cessation outweighs the increased risk of seizure.

For full list of interactions check latest SPC[5]

[5] https://www.medicines.org.uk/emc/product/3827#INTERACTIONS

GP Prescribing Protocol- Bupropion Hydrochloride for Smoking Cessation

Clients using the local smoking cessation services and wishing to use Bupropion Hydrochloride will be referred to their own GP with an accompanying letter/prescription request form. The GP will make a clinical assessment of the client to establish their suitability for Bupropion Hydrochloride. It remains the clinical decision of each individual GP as to whether a prescription for Bupropion Hydrochloride is issued. **Decision to prescribe?**

Do not use Bupropion Hydrochloride with those who are/ have:

- Under 18 years old
- Pregnant and/or breastfeeding
- A history of seizures, bipolar disorder or eating disorder
- A acute alcohol or benzodiazepine withdrawal
- Severe hepatic cirrhosis
- CNS tumour
- Heart disease
- Using Antidepressants and/or Antimalarials
- Sedating antihistamines

Refer client back to the smoking cessation service/advisor for further advice and assessment for NRT to be considered as part of the treatment programme.

Caution: do any of the following apply?

- Client has a history of psychiatric illness
- Client has heart disease
- Client has COPD
- Has mild to moderate renal impairment
- Diabetes
- Client has hepatic impairment and Diabetes

Yes

No

Is the condition stable and regularly monitored?

Yes

A quit date is set for two weeks time and a follow up appointment should be arranged with the stop smoking advisor.

Prescribe Bupropion Hydrochloride for a maximum 8 week course at 2-3 weekly intervals in conjunction with behavioural support and regular monitoring sessions (including mood and blood pressure weekly) with a smoking cessation advisor.

Day 1 – 6	150mg	Once daily
Day 7 to end of treatment (8 wks)	150mg	Twice daily (8 hours between each dose)

Monitor progress and reassess for any adverse events every 2 -4 weeks for the 8 week treatment duration

Please note: Ensure prescription is 'Acute' only and consider dose tapering on completion of 8 week course

Please note: If full dose cannot be tolerated lower dose to 150mg once daily. For the elderly the dose is 150mg once daily.

Reviewed Feb 2018

APPENDIX 5

CLINICALLY SIGNIFICANT DRUG INTERACTIONS

The following criteria have been considered in grading clinical relevance of drug interactions:
High: Documented pharmacokinetic interaction with clinically important effects in a number of patients.
Moderate: Documented pharmacokinetic interaction with minor clinical effects, or isolated reports of clinically important effects.
Table. 1 Clinically significant drug interactions with cigarette smoking.

Drug name	Nature of interaction	Clinical relevance	Action
Aminophylline Theophylline	Aminophylline is a stable mixture of theophylline and ethylenediamine. Theophylline and aminophylline are metabolised principally via CYP1A2, therefore clearance is increased in smokers. Heavy smokers (20-40 cigarettes per day) may need much higher doses than non-smokers, due to the shortened theophylline half-life and increased elimination rate	HIGH	When stopping smoking, a reduction in theophylline dose of up to 25-33% might be needed after one week. However, it may take several weeks for enzyme induction to dissipate. Monitor plasma theophylline concentrations and adjust theophylline dose accordingly. Advise the patient to seek help if they develop signs of theophylline toxicity such as vomiting, diarrhoea, palpitations, nausea or vomiting
Clozapine	Clozapine is metabolised principally via CYP1A2 therefore clearance is increased in smoker. Smoking reduces plasma levels of clozapine by up to 50% so smokers may need higher doses. Likewise, patients who stop smoking may experience a 50% increase in plasma level so will need dose reduction	HIGH	Blood levels of clozapine should be measured before stopping or restarting smoking. On stopping smoking, reduce dose gradually over a week until around 75% of original dose reached (i.e. reduce by 25%). Repeat plasma level one week after stopping smoking. Anticipate further dose reductions If re-starting smoking take a plasma level before re-starting. Increase dose to previous smoking dose over one week. Repeat plasma level
Olanzapine	Olanzapine is metabolised principally via CYP1A2 and clearance is increased in smokers. Serum olanzapine levels are reduced in smokers compared with nonsmokers; smokers may need higher doses.	HIGH	On stopping smoking, reduce dose by 25%. Consider further dose reductions. Be alert for increased adverse effects of olanzapine such as dizziness, sedation, and hypotension. If adverse effects occur, reduce the dose as necessary
Erlotinib	Erlotinib is metabolised primarily by CYP3A4 and to a lesser extent CYP1A2. Smokers have an increased rate of erlotinib clearance leading to decreased drug exposure.	HIGH	Current smokers should be advised to stop smoking prior to starting treatment. When given to patients who smoke, increase the daily dose in 50mg increments at 2-week intervals, up to a maximum dose of 300mg. If the patient stops smoking the dose should be immediately reduced to the initial starting dose

Riociguat	Riociguat is metabolised by CYP1A1, CYP3A4, CYP3A5 and CYP2J2. In cigarette smoking, riociguat exposure is reduced by 50-60%	HIGH	Current smokers should be advised to stop smoking prior to starting treatment. A dose increase to the maximum of 2.5mg three times a day may be needed in patients who are smoking or start smoking during treatment. If the patient stops smoking during treatment the dose may need to be reduced
Warfarin	Warfarin is partly metabolised via CYP1A2.	MODERATE	Monitor smoking status during warfarin therapy. If a patient taking warfarin changes their smoking status this may increase their INR. In such cases, monitor INR more closely and adjust dose as needed. Advise patients to tell the healthcare professional managing their anticoagulant control that they are changing their smoking status
Chlorpromazine	Chlorpromazine is extensively metabolised in the liver. Smokers have lower serum levels of chlorpromazine compared with non-smokers.	MODERATE	Monitor patient closely if they plan to abruptly stop smoking and consider a dose reduction. Advise patients who smoke or who start to smoke to be alert for increased adverse effects of chlorpromazine (e.g. dizziness, sedation, nausea). If adverse effects occur, reduce the dose as necessary
Methadone	Methadone is extensively metabolised in the liver by CYP isoenzymes including CYP1A2	MODERATE	Monitor patient closely if they plan to abruptly stop smoking. Advise patients who plan to abruptly stop smoking to be alert for signs of opioid toxicity. Reduce methadone dose accordingly

Summary: Most interactions between drugs and smoking are not clinically significant. • Healthcare professionals giving smoking cessation advice should be aware of a small number of medicines, in particular aminophylline, theophylline, clozapine, olanzapine, erlotinib and riociguat, which may require dose adjustment or increased monitoring when smoking status is altered. • Patients taking narrow-therapeutic-index drugs should be monitored closely when any lifestyle modification is made.

Limitations: This Q&A does not include drugs which have a low risk, theoretical interaction without documented cases and/or drugs metabolised partly by CYP1A2 and with a wide therapeutic range. • It does not consider interactions with pharmacological agents used for smoking cessation (e.g. bupropion, varenicline), or pharmacodynamics interactions (e.g. effects of smoking on blood pressure). It does not include potential interactions of e-cigarettes.

Reference: https://www.sps.nhs.uk/wp-content/uploads/2017/11/UKMI_QA_Drug-interactions-with-smoking-cigarettes_update_Nov-2017.pdf

GLOSSARY

LEVELS OF SERVICE (NICE)
Level 1: Brief Interventions
Level 2: Intensive 1:1 support and advice
Level 3: Group interventions
Produced by -
Review Date: February 2019
Next review due before: February 2020

Lot 4: Public Health Community Pharmacy Contract NRT Voucher Scheme

Service Specification: Nicotine Replacement Therapy Pharmacy Voucher Scheme 2019-20

Contents

Context

Cambridgeshire County Council and Peterborough City Council commission stop smoking services from community pharmacies for their local populations. Both local authorities are working more closely together which reflects the footprint of the Cambridgeshire and Peterborough Clinical Commissioning Group. Consequently there are a number of Joint Commissioning Units emerging including the Cambridgeshire and Peterborough Public Health Joint Commissioning Unit (JCU). The Public Health JCU launched May 1st 2017 commissioning responsibilities will include the services that are provided by primary care. The aim is to standardise the commissioned primary care services across the CCG footprint. Although the JCU will work across the two local authority areas, individual community pharmacy contracts will be contracted by the local authority where they are geographically located. Staff from the JCU will continue to support community pharmacies where appropriate as well have a performance management function.

1. Service Description

This smoking cessation service will be provided by trained community pharmacy staff as an enhanced service. The service will be provided in a pharmacy setting. It will include the provision of pharmacological products to aid the cessation attempt but does not include one to one behavioural support which will be provided by a local CAMQUIT advisor or School Nurse.

2. Aims of Community Pharmacy Smoking Cessation NRT Voucher Scheme

2.1 If the pharmacy does not wish to participate in the full pharmacy scheme then they can sign up to participate in the Cambridgeshire voucher pharmacy scheme.

2.2 To dispense pharmacological products to support a cessation attempt by facilitating the NRT voucher scheme.

3. Recipients

3.1 This service may be offered to a smoker who would like to make a quit attempt using a licensed nicotine containing product (NRT) as part of a standard treatment programme.

3.2 This service may be offered to anyone over the age of 12 years, most NRT products are licensed for 12 year olds plus.

3.3 The contractor is required to dispense NRT upon receipt of a valid NRT Voucher. Clients will be receiving behavioural support from an external provider; therefore the contractor is NOT required to provide additional

support. However the Pharmacy should provide brief advice and instructions on how to use the product effectively.

3.4 Pharmacies will supply NRT on receipt of a voucher from an authorised individual as directed on the voucher. Pharmacies will confirm that the NRT has been supplied as directed and will record the dispensed medication via the PharmOutcomes system and keep all vouchers and related paperwork for routine audit purposes.

3.5 The Public Health Joint Commissioning Unit (JCU) will generate a monthly summary report through the Commissioners portal and this will be used to make a payment. No patient identifiable information will be shared with the Commissioner. Cambridgeshire & Peterborough Public Health request that all commissioned Public Health interventions are recorded on the web-based platform PharmOutcomes.

3.6 All clients accessing this scheme will be provided with stop smoking advice by the smoking cessation advisor completing the voucher. Pharmacies will only be required to supply the requested product. Patients should be directed back to their smoking cessation advisor for further stop smoking advice or to obtain another voucher for NRT. This is also an opportunity for the Pharmacist to offer the pharmacy scheme if this option is easier for the client.

3.7 The EC Labelling and Leaflet Directive applies to all NRT supplied. The pack should be labelled with the following information:

- The address of the clinical area where the supply was made
- 'Keep out of the reach of children'
- Directions for use
- The name of the patient
- Date of supply
- The pharmacy is not required to staple the prescription receipt to the monitoring form.

3.8 If the voucher has **not** been signed by the authorised smoking cessation advisor then the supply **should not** be made and should be signposted back to their original advisor or could be signed up on the community pharmacy scheme.

3.9 Vouchers will be valid for two weeks from date stated by Smoking Cessation Advisor. Clients who present an out of date voucher should be signposted back to their original advisor or can be signed up on the community pharmacy scheme if this is a suitable programme for the client.

3.10 NRT supplied should be in accordance with the dispensing essential service.

3.11 If the directions on the voucher are not clear then the smoking cessation advisor should be contacted for clarification.

3.12 If patients are exempt from NHS prescription charges then there is no charge to the client for supply of NRT through this scheme. Clients accessing the service who are not exempt from prescription charges will be

required to pay one prescription charge per product for each 2 week cycle of NRT supplied. The NHS prescription pre-payment scheme should be promoted to the client. The cost of NRT will be reimbursed to the pharmacy through the voucher minus any prescription charges.

3.13 NRT products are licensed for over 12 year olds. As part of Public Health's commitment to reduce the prevalence of smoking in young people, Camquit supports the school nurse team to provide NRT products via the voucher scheme.

3.14 It is the Pharmacists responsibility for the treatment of the smoker and therefore he/she should only dispense the product suggested on the voucher should they deem it appropriate to do so.

4. Payment and data return

The fee structure for community pharmacy participation in the scheme will be:

- Pharmacies will be paid £2.50 for each NRT product dispensed on receipt of voucher. On dispensing the product the Pharmacy should provide the client with brief advice and instructions on the product use.
- Pharmacies will be reimbursed for NRT supplied at drug tariff cost set for the financial year as per the BNF values on 1st April 2019. Tariff costs will be reviewed and renewed on an annual basis.
- Summary information about all Vouchers must be recorded on the PharmOutcomes system. A Commissioner's report will be generated and used to process contract payments.

5. Core Skills and Training

Smoking cessation training is compulsory for every staff member involved in the provision of the voucher scheme.

The pharmacy contractor has the responsibility to ensure that all staff including locums involved in providing the service are appropriately trained i.e. attendance at a Cambridgeshire or Peterborough organised smoking cessation training programme.

The pharmacy contractor has the responsibility to ensure that pharmacists and staff involved in the provision of the service are aware of and act in accordance with the Service Specification, the Joint Commissioning Unit, Cambridgeshire County Council protocols, best practice guidance and NICE guidance.

The pharmacy contractor has the responsibility to ensure that their service has the recommended quality controls in place and that the service can demonstrate compliance.

Training will be provided free of charge locally as agreed by the JCU and will be provided by accredited trainers. The level of training should be brief intervention training and also an induction into the local service and NRT products (maximum 2 hours).

All advisors are encouraged to access the nationally accredited certification which is available free of charge via the National Centre for Smoking Cessation Training website www.ncsct.co.uk.

6. Commissioner responsibilities

- Cambridgeshire County Council reimburses the pharmacy for the cost of NRT and a dispensing fee based on information each pharmacy provides to the Joint Commissioning Unit.
- The Commissioner will provide details of relevant referral points which pharmacy staff can use to signpost service users who require further assistance.

7. Pharmacy Responsibilities

- The pharmacy will complete the community pharmacy voucher for each client on the PharmOutcomes system.
- The pharmacy reviews its standard operating procedures and the referral pathways for the service.
- The pharmacy will maintain links with local smoking cessation services to ensure that referral pathways are maintained.
- The pharmacy can demonstrate that pharmacists and staff involved in the provision of the service have undertaken CPD relevant to this service and locally organised training provided by accredited trainers.
- The pharmacy participates in an annual Cambridgeshire County Council organised audit of service provision.
- The pharmacy co-operates with any locally agreed led assessment of service user experience.
- The pharmacy should inform the Commissioner if they are no longer able to participate in the scheme due to movement of trained staff or if they no longer wish to participate in the scheme. A minimum of one month's notice period should be given to the Commissioner should the Pharmacy wish to terminate or temporarily put the service on hold.

Appendix A- Smoking Cessation voucher NRT VOUCHER FOR COMMUNITY PHARMACY SUPPLY

CLIENT: Please take this form to a participating pharmacy (see below) within TWO WEEKS of initial consultation to obtain your NRT product and complete the prescription charge/exemption information overleaf.
SMOKING ADVISOR: Please complete fully and void products not required.

Client name:		**Advisor name (please print):**	**OFFICE USE ONLY** Date Received
Client address: **Postcode:**		**Advisor signature:**	
Prescription exemption code (if applicable)		**Contact number:** **Date:**	

Void products NOT to be prescribed	**Product**	**Dose**	**2 weeks supply**	**State prescription charge paid if applicable**	**Brand (to be completed by pharmacy staff)**
☐	Patch 16 hour	25mg ☐15mg ☐ 10mg ☐	14 ☐		
☐	Patch 24 hour	21mg ☐14mg ☐ 7mg ☐	14 ☐		
☐	Gum	4mg ☐ 2mg ☐	2 x 105 ☐ 2 x 96 ☐		
☐	Mini Lozenge	4mg ☐ 1.5mg☐	4 x 60 ☐		
☐	Cools Lozenge	4mg ☐ 2mg ☐	3 x 80 ☐		
☐	Lozenge	4mg ☐ 2mg ☐	4 x 96 ☐ 2 x 96 ☐		
☐	Inhalator	15mg☐	3 x 36 ☐ 4 x 20 ☐		
☐	Mouth spray	1mg ☐	3 x duo packs ☐		
☐	Oral Strips	2.5mg ☐	4 x 60 ☐		
☐	Micro tablet	2mg ☐	5 x 105 ☐		
☐	Nasal Spray	0.5mg ☐	5 units ☐		

Note to pharmacist from advisor	
PHARMACY STAFF: Please supply NRT as directed above, add the brand of product/s dispensed, complete the information below and return the voucher for payment.	

Pharmacist signature:	**Date:**
Pharmacy name/address/stamp:	**Please return completed forms to:** Camquit Cambridgeshire County Council Box No CC1318 Castle Court Cambridge CB3 0AP

I confirm that the NRT requested above was supplied to the above client.

PRESCRIPTION CHARGE/EXEMPTION INFORMATION

To the client: Patients who don't have to pay must fill in parts 1 and 3. Those who pay must fill in parts 2 and 3.

Part 1	The patient doesn't have to pay because he/she:
A ❒	Is under 16 years of age
B ❒	Is 18 years of age and in full-time education
C ❒	Is 60 years of age or over
D ❒	Has a valid maternity exemption certificate
E ❒	Has a valid medical exemption certificate
F ❒	Has a valid prescription prepayment certificate
G ❒	Has a War Pension exemption certificate
L ❒	Is named on a current HC2 charges certificate
H ❒	Gets Income Support (IS)*
K ❒	Gets Income-based Jobseeker's Allowance (JSA (IB))*
M ❒	Is entitled to, or named on, a valid NHS Tax Credit Exemption Certificate*
S ❒	Has a partner who gets Pension Credit guarantee credit (PCGC)*

* If benefit or tax credit is paid to your partner or someone else for you, give their details here:

Declaration For patients who do not have to pay	I declare that the information I have given on this form is correct and complete. I understand that if it is not, appropriate action may be taken. I confirm proper entitlement to exemption. To enable the NHS to check I have a valid exemption and to prevent and detect fraud and incorrectness, I consent to the disclosure of relevant information from this form to and by the NHS Business Services Authority, the NHS Counter Fraud and Security Management Service, the Department for Work and Pensions and Local Authorities. **Now sign and fill in Part 3**
Part 2	I have paid £ **Now sign and fill in Part 3**
Part 3	Cross ONE box I am the patient ❒ patient's representative ❒
Sign here:	Date / /

Schedule 2 Service Performance

1. INTRODUCTION

1.1 The Service Provider's performance shall be monitored by the Authority in relation to service provision and quality.

2. QUALITY OF SERVICE

The Authority regards the quality of service as very important, and the Service Provider shall take all reasonable steps to ensure that the Services are provided to the required quality as set out in this agreement.

Schedule 3 Service Provider's Tender

Not Applicable

Schedule 4 Charge Variation

Not Applicable

Schedule 5 Contract management

3. AUTHORISED REPRESENTATIVES

3.1 The Authority's initial Authorised Representative: **Val Thomas, Consultant in Public Health, Shire Hall, Cambridge, CB3 0AP**

3.2 The Service Provider's initial Authorised Representative**: [INSERT DETAILS]**

Schedule 6 Change control

1. GENERAL PRINCIPLES

1.1 Except as otherwise provided for in this agreement, where the Authority or the Service Provider sees a need to change this agreement, the Authority may at any time request, and the Service Provider may at any time recommend, such Change only in accordance with the Change Control Procedure set out in paragraph 2 of this 0.

1.2 Until such time as a Change is made in accordance with the Change Control Procedure, the Authority and the Service Provider shall, unless otherwise agreed in writing, continue to perform this agreement in compliance with its terms before such Change.

1.3 Any discussions which may take place between the Authority and the Service Provider in connection with a request or recommendation before the authorisation of a resultant Change shall be without prejudice to the rights of either party.

1.4 Any work undertaken by the Service Provider and the Service Provider's Personnel which has not been authorised in advance by a Change, and which has not been otherwise agreed in accordance with the provisions of this 0, shall be undertaken entirely at the expense and liability of the Service Provider.

2. PROCEDURE

2.1 Where the Authority or the Service Provider requests a Change to this agreement, the requesting party must notify the other party of such a request in writing providing full details of the request (including any implications on the Charges).

2.2 If the Change is requested by the Authority and would not in the reasonable opinion of the Authority materially change the nature of the agreement, the Service Provider shall implement the requested Change with no alteration to the Charges.

2.3 For the avoidance of doubt, if a Change is requested by the Service Provider which would not in the reasonable opinion of the Authority materially change the nature of the agreement, the Authority may in its discretion approve such

a Change PROVIDED THAT the Service Provider shall not be entitled to vary the Charges as a result of such a Change.

2.4 For the purpose of paragraphs 2.2 and 2.3, a material change to the nature of the agreement shall include but not be limited to alterations to the Specification;

2.5 For any Change not covered by paragraphs 2.2 to 2.4, the parties shall seek to agree any Changes at any time in writing.

2.6 Where the request for a Change is made by the Authority and the Changes (including any variations to the Charges) cannot be agreed with the Service Provider within a reasonable period of time (to be determined by the Authority in its discretion acting reasonably), the Authority shall be entitled to terminate this agreement and the provisions of clauses 26 and 29 shall apply.

2.7 Where the request for a Change is made by the Service Provider and the Changes (including any variations to the Charges) cannot be agreed with the Authority within a reasonable period of time (to be determined by the Authority in its discretion acting reasonably), the Authority shall be entitled to refuse such a Change.

2.8 Where a Change to the agreement is agreed between the parties (including a variation to the Charges), a written record of that Change shall be prepared by the Authority and signed by an authorised representative of both parties. Such a written record shall constitute an amendment to this agreement and a copy of the same (as signed by both parties) shall be appended to this agreement. Any agreed Change (including a variation to the Charges) shall come into effect on the date for implementation to be agreed between the parties.

Schedule 7 Exit Management Plan

Not Applicable

Schedule 8 Healthcare Specific Requirements

Schedule 9 Commercially sensitive information

[DETAILS OF ANY SERVICE PROVIDER INFORMATION TO BE CLASSIFIED AS COMMERCIALLY SENSITIVE]

Not Applicable

Schedule 10 Authority's Premises and Assets

NOT USED

Schedule 11: Agreed Changes

Not Applicable

Schedule 12 Data Processing

1. The Service Provider shall comply with any further written instructions with respect to the processing by the Authority.
2. Any such further instructions shall be incorporated into this schedule.

Description	Details
Subject matter of the processing	Initial recording, consideration and consultation of Personal Data in connection with the Service Provider's Services.
Duration of the processing	The personal data processed by the Service Provider and/or the Authority will be subject to this processing operations for the duration of the Agreement (4 years) and subsequently where such retention is required by applicable law or for actual or prospective legal claims or as otherwise set out by either Party.
Nature and Purposes of the processing	Data collection and processing to support the Service Provider to deliver Service and to enable reporting to the Authority to confirm whether the Service Provider is delivering outcomes outlined in the DPS. Personal data will be processed by the Service Provider and/or the Authority in order for: - the Service Provider to provide the Services under this Agreement; - the Service Provider to maintain records required for provision of the Service; - the Service Provider to invoice and receive payment from the Authority; and - quality assurance, performance management and contract management by the Authority.

Type of Personal Data	Personal Data will be Processed by the Service Provider under Article 6(1)(e) and Article 9(2)(h) of the GDPR and will include: - data which identifies the recipients of the Service - such as name, contact details (which may include address, email address or phone number) and date of birth/age; - data relating to the health of the recipient and details of any test or treatment provided by the Service Provider (special category data); - GP details (including name and practice details) where required [*delete if not applicable*] - financial data of recipients of the Service where payment may be required for the Service [*delete if not applicable*] - financial data of the Parties in order to invoice and receive payment for Services.
Categories of Data Subject	Data collection and processing to support the Service Provider to deliver Service and to enable reporting to the Authority to confirm whether the Service Provider is delivering outcomes outlined in the contract.
Plan for return and destruction of the data once the processing is complete UNLESS it is a requirement under union or member state law to preserve that type of data	

Schedule 13 Service Level agreement – platform lease

PharmOutcomes/Outcomes4Health Service Level Agreement V5 1
DATED 01st April 2019
(1) Pinnacle Health Partnership LLP
(2) Cambridgeshire County Council
SERVICE LEVEL AGREEMENT

PharmOutcomes/Outcomes4Health Service Level Agreement V5 2
THIS AGREEMENT is made the day of 1st April 2019
BETWEEN:
(1) Pinnacle Health Partnership LLP a company registered in England under number OC347501 whose registered office is at 1st Floor, Weatherwise Building, Well Road, East Cowes, PO32 6SP ("the Service Provider"); and
(2) Cambridgeshire County Council, Shire Hall, Cambridge, CB3 0AP ("the Service Commissioner")
WHEREAS:
(1) The Service Provider is engaged in the business of providing services in relation to the provision of web-based clinical record and service management system and has reasonable skill, knowledge, qualifications and experience in that field.
(2) The Service Commissioner wishes to engage the Service Provider to provide the Services detailed in Schedule 1, subject to, and in accordance with, the terms and conditions of this Agreement.
(3) The Service Provider has agreed to accept such engagement and shall provide the Services to the Service Commissioner, subject to, and in accordance with, the terms and conditions of this Agreement.
(4) This agreement is intended to be a Data Processing Agreement, for the purposes of the General Data Protection Regulation 2018 (GDPR), between the Service Commissioner as a data controller, and the Service Provider as a data processor.

IT IS AGREED as follows:
1. Definitions and Interpretation
1.1. In this Agreement, unless the context otherwise requires, the following expressions have the following meanings:
"Adequate Procedures" means adequate procedures, as referred to in section 7(2) of the Bribery Act 2010, and any guidance issued by the Secretary of State under section 9 of the Bribery Act 2010;
"Affiliate" means any person, company, partnership or other entity which directly or indirectly controls or is controlled by a Party and any company of which it is a member and any partnership of a partner;
"Agreement Review" means a review of this Agreement which shall be conducted in accordance with Clause 8 at the intervals specified in that Clause;
"Anti-Corruption Legislation" means the Bribery Act 2010 and any other applicable laws and regulations prohibiting public or commercial bribery, extortion, kickbacks or other unlawful or improper means of

conducting business;
“Associated Persons” means in relation to a company, a person (including an employee, agent or subsidiary) who performs services for or on that company’s behalf;
“Business Day” means any day (other than Saturday or Sunday) on which ordinary banks are open for their full range of normal business in the area provided for;
“Commencement Date” means the date on which this Agreement comes into force pursuant to Clause 2 below;
“Confidential Information” means, in relation to any Party, information which is disclosed to that Party by a Party pursuant to or in connection with this Agreement (whether orally or in writing or any other medium, and whether or not the information is expressly stated to be confidential or marked as such);
“The System”,
“PharmOutcomes” and
“Outcomes4Health” means the system detailed at Schedule 1;
“Data Controller”.
“Data Processor”,
“processing”
and Data Subject shall have the same meaning as the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679), and the Data Protection Act 2018
In the case of PharmOutcomes/Outcomes4Health these are:
Service Commissioner – Data Controller; Pinnacle Health Partnership – Data Processor;
Clinical Service Providers – Data Controller and Data Processor.
“Data Protection Legislation” means the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679), and the Data Protection Act 2018, the Regulation of Investigatory Powers Act 2000, the Telecommunications (Lawful Business Practice) (Interception of Communications) Regulations 2010 (SI2000/2699), the Electronic Communications Data Protection Directive 2002/58/EC and subsequent amendments, the Privacy and Electronic Communications (EC Directive) Regulations 2003 and all applicable laws and regulations relating to processing of personal data and privacy including, where applicable, the guidance and codes of practice issued by the Information Commissioner;

“Fees” means the fees payable by the Service Commissioner to the Service Provider in accordance with Clause 6 and Schedule 2;
“ICO” means the Information Commissioner’s Office
“Intellectual Property Rights” means any and all patents, rights in inventions, rights in designs, trademarks, trade and business names and all associated goodwill, rights to sue for passing-off or for unfair competition, copyright, moral rights and related rights, rights in databases, topography rights, domain names, rights in information (including know-how and trade secrets) and all other similar or equivalent rights (subsisting now or in the future) in any part of the world, in each case whether registered or unregistered and including all applications for, and renewals or extensions of, such rights for their full term;

“Law” means any applicable law, statute, bye-law, regulation, order, regulatory policy, guidance or industry code, rule of court or directives or requirements of any regulatory body or delegated subordinate legislation or notice of any regulatory body;
“Location” shall mean the locations detailed at Schedule 1;
“Modifications” means any update to The System which correct faults issued by the Service Provider in its sole discretion from time to time but which does not add functionality or otherwise amend or upgrade The System;
“Performance Report” means a report detailing the performance of the Services in relation to the Service Levels, prepared in accordance with the provisions of Schedule 3;
“Personal Data” shall have the meaning set out in the GDPR, and the Data Protection Act 2018
“Security Measures” means the security measures set out in Clause 29.
“Services” means the provision of The System to the Service Commissioner during the Term, as described in Schedule 1, in accordance with the terms and conditions of this Agreement;
“Service Levels” means the agreed levels to which the Service Provider’s performance in providing the Service must adhere as set out Schedule 3;
“Service Commissioner Data” all data or information, in whatever form (including images, still and moving, and sound recordings) from the Service Commissioner;
“Service Provider’s
Representative” means the nominated individual who shall be responsible for liaising with the Service Commissioner’s Representative in
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accordance with Clause 8, or such other person who the Service Provider may from time to time nominate;
“Service Provider’s
Management Representative” means the nominated individual who shall be responsible for liaising with the Service Commissioners’ Management Representative in accordance with Clause 8, or such other person who the Service Provider may from time to time nominate;
“Service Provider’s
Performance Representative” means the nominated individual who shall be responsible for the monitoring of the provision of the Services in accordance with the Service Levels under Clause 9, or such other person who the Service Provider may from time to time nominate;
“System Users” means the users of The System recording service provisions.
“Term” means the term of this Agreement as set out in Clause 2.

1.2. Unless the context otherwise requires, each reference in this Agreement to:
1.2.1. “writing” includes a reference to any communication effected by electronic or facsimile transmission or helpdesk support ticket;
1.2.2. a statute or a provision of a statute is a reference to that statute or provision as amended or re-enacted at the relevant time;
1.2.3. “this Agreement” is a reference to this Agreement and each of the Schedules as amended or supplemented at the relevant time;

1.2.4. a Schedule is a schedule to this Agreement; and
1.2.5. a Clause or paragraph is a reference to a Clause of this Agreement (other than the Schedules) or a paragraph of the relevant Schedule.
1.2.6. a "Party" or the "Parties" refer to the parties to this Agreement.

1.3. The headings used in this Agreement are for convenience only and shall have no effect upon the interpretation of this Agreement.

1.4. Words denoting the singular shall include the plural and vice versa, words denoting a gender shall include all genders and words denoting persons shall include corporations and all other legal entities.

2. Term of Agreement
2.1. This Agreement shall come into force on the agreed Commencement Date shown in Schedule 2 and shall continue in force from that date for an initial term listed in Schedule 2, subject to the provisions of Clauses 8 and 12.
2.2. Subject to the Agreement Review provisions of Clause 8, the Term of this Agreement may be renewed (any renewal period shall thereafter be defined as part of the Term).

3. Service Provider's Obligations
3.1. The Service Provider shall provide the Services to the Service Commissioner in accordance
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with the provisions of Clause 7, and in accordance with the required Service Levels set out in Schedule 3.
3.2. The Service Provider shall perform its obligations under this Agreement in a reasonable and timely manner in accordance with the provisions of this Agreement and shall exercise proper professional skill, care and diligence in the performance of the Services.
3.3. The Service Provider shall provide the Service Commissioner with such information and advice in connection with the Services and the provision thereof as the Service Commissioner may, from time to time, reasonably require both before and during the provision of the Services.
3.4. The Service Provider shall use its reasonable endeavours to keep the Service Commissioner informed of any special requirements (including, but not limited to, legislative requirements) applicable to the rendering of the Services. To the extent necessary and appropriate, the Service Provider shall take steps as soon as reasonably possible to comply with any such requirements. These steps shall not otherwise alter this Agreement in any way, subject to each Party's right under sub-Clause 8.4 to request a meeting to review such changes.
3.5. Subject to its obligations to comply with the Service Levels, the Service Provider shall use reasonable endeavours to ensure that the Services shall be uninterrupted or error-free. During the Term of this Agreement, the Service Commissioner shall promptly notify the Service Provider in writing in the event that there is a fault with The System (providing as much detail of the fault as possible) and the Service

Provider shall act in accordance with clause 3.2 to try to resolve that fault. The Service Provider may provide any Modifications that it deems appropriate to fix that fault to the Service Commissioner at no additional cost to the Service Commissioner.

4. Exclusivity

4.1. During the Term of this Agreement neither Party nor any of its Affiliates shall induce solicit or entice, or endeavour to induce, solicit or entice away from the other Party or employ any person who at any time during the Term is employed by the other Party or who is a consultant to the other Party and with whom the first Party has come into contact as a result of this Agreement or this Project. If a Party is in breach of this clause 4.1 then, without limiting any other right or remedy which the other Party may have pursuant to such breach, the Party in breach shall reimburse such other Party in respect of all charges, fees, costs and expenses reasonably paid by that Party to any recruitment agencies or other third parties in consideration of the provision by such agency or third party of recruitment services for the purpose of the recruitment of a replacement for the employee so enticed or solicited.

4.2. Nothing in this Agreement shall prevent the Service Commissioner from appointing or procuring the provision by a third party of any services the same as or similar to the Services.

5. Service Commissioners' Obligations

5.1. The Service Commissioner shall provide the Service Provider with such information in connection with the Services and the provision thereof as the Service Provider may, from time to time, reasonably require both before and during the provision of the Services.

5.2. The Service Commissioner shall perform their obligations under this Agreement in a reasonable and timely manner in accordance with the provisions of this Agreement.

5.3. The Service Commissioner shall use reasonable endeavours to keep the Service Provider

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informed of any special requirements (including, but not limited to, legislative requirements) applicable to the rendering of the Services. To the extent necessary and appropriate, the Service Provider shall (as under sub-Clause 3.4) promptly take steps to comply with any such requirements. These steps shall not otherwise alter this Agreement in any way, subject to each Party's right under sub-Clause 8.4 to request a meeting to review such changes.

6. Fees, Payment and Records

6.1. The Service Provider shall invoice the Service Commissioner for the amounts detailed under Licence Fees in Schedule 2 as consideration for the Services provided by the Service Provider and for the licence of The System in accordance with the terms and conditions of this Agreement.

6.1.1. The Service Provider shall invoice the Service Commissioner in respect of any services as referred to in paragraphs 1 and 2 of Schedule 2 that it provides to the Service Commissioner (which services shall be carried out by the Service Provider

with reasonable skill and care and in accordance with all good industry practice) following the proper provision of those services.
6.2. All payments required to be made pursuant to this Agreement by the Service Commissioner shall be made within thirty days of receipt of the relevant invoice in sterling in cleared funds to such bank in England as the Service Provider may from time to time nominate.
6.3. All Fees are exclusive of value added tax, which the Service Provider shall add to its invoices at the appropriate rate.
6.4. The Service Commissioner shall be entitled to set-off, withhold or deduct any liability of the Service Provider to the Service Commissioner against any liability of the Service Commissioner to the Service Provider, whether or not such liability is present or future, liquidated or unliquidated, and whether or not such liability arises under this Agreement.
6.5. Where any payment pursuant to this Agreement is required to be made on a day which is not a Business Day, it may be made on the next following Business Day.
6.6. If the Service Commissioner fails to pay on the due date any amount which is payable to the Service Provider pursuant to this Agreement then, without prejudice to and notwithstanding Clause 12.3, that amount shall bear interest from the due date until payment is made in full, both before and after any judgment, at a rate of 2% per annum over the Bank of England base rate from time to time in force.

7. Provision of the Services
7.1. The Service Provider shall, throughout the Term, provide the Services to the Service Commissioner in accordance with the terms and conditions of this Agreement, including the Service Levels as specified in Schedule 3.
7.2. The Service Provider shall provide the Services only as specified in Schedule 1 unless otherwise agreed in writing by the Service Commissioner.
7.3. The Service Provider shall be responsible for ensuring that it complies with all statutes, regulations, byelaws, standards, codes of conduct and any other rules relevant to the provision of the Services.
7.4. The Service Provider shall use reasonable endeavours to ensure that the manner in which it provides the Services does not have any adverse effect on the name, reputation, image or business of the Service Commissioner.
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8. Service and Agreement Monitoring
8.1. The Service Commissioner and the Service Provider may arrange meetings between the Service Commissioners' Representative and the Service Provider's Representative from time to time by teleconference in order to discuss the provision of the Services in accordance with the Service Levels, where necessary.
8.2. The Service Commissioner and the Service Provider may arrange meetings by teleconference between the Service Commissioners' Management Representative and the Service Provider's Management Representative when required in order to discuss matters arising out of meetings held pursuant to sub-Clause 8.1 and any other matters including, but not limited to, those relating to the provision of the Services and the Service Levels.

8.3. No later than 3 months prior to the end of the current Term of this Agreement, the Service Commissioners' Management Representative and the Service Provider's Management Representative shall conduct an Agreement Review during which the continuance and renewal of this Agreement shall be determined. In the event that a renewal of the Agreement is agreed upon in writing and signed by all Parties, the provisions of sub-Clause 2.2 shall apply.
8.4. Notwithstanding the provisions of sub-Clause 8.2, in the event that changes to this Agreement are required due to circumstances including, but not limited to, legislative or regulatory change, any Party shall have the right to call for an immediate Agreement Review to discuss the necessary changes and action to be taken. Any changes agreed upon during such Agreement Reviews shall not be effective unless evidenced in writing and signed by the duly authorised representatives of the Service Commissioner and the Service Provider.

9. Performance Management and Monitoring
For the purposes of monitoring and managing performance under this Agreement the Parties shall respectively appoint the Service Commissioners' Performance Representative and the Service Provider's Performance Representative (each a "Performance Representative" for the purposes of this Clause 9). It shall be the responsibility of the Performance Representatives to ensure that the Services are provided in accordance with the Service Levels and the terms and conditions of this Agreement.

10. Confidentiality
10.1. Each Party undertakes that, except as provided by sub-Clause 10.2 or as authorised in writing by the disclosing Party, it shall, at all times during the continuance of this Agreement and after its termination:
10.1.1. keep confidential all Confidential Information;
10.1.2. not disclose any Confidential Information to any other person;
10.1.3. not use any Confidential Information for any purpose other than as contemplated by and subject to the terms and conditions of this Agreement;
10.1.4. not make any copies of, record in any way or part with possession of any Confidential Information; and
10.1.5. ensure that none of its directors, partners, officers, employees, agents or advisers does any act which, if done by that Party, would be a breach of the provisions of sub-clauses 10.1.1 to 10.1.4 above.
10.2. Each Party may:
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10.2.1. disclose any Confidential Information to:
10.2.1.1. any sub-contractor or supplier of that Party;
10.2.1.2. any governmental or other authority or regulatory body; or
10.2.1.3. any employee or officer of that Party or of any of the aforementioned persons, parties or bodies;
10.2.2. to such extent only as is necessary for the purposes contemplated by this Agreement, or as required by law, and in each case subject to that Party first informing the person, party or body in question that the Confidential Information is

confidential and (except where the disclosure is to any such body as is mentioned in sub-Clause 10.2.1.2 above or any employee or officer of any such body) obtaining and submitting to the other Party a written undertaking from the person in question, as nearly as practicable in the terms of this Clause 10, to keep the Confidential Information confidential and to use it only for the purposes for which the disclosure is made;
10.2.3. such extent only where aggregated and anonymised information are used for the purposes of analysis, performance and good practice; and
10.2.4. use any Confidential Information for any purpose, or disclose it to any other person, to the extent only that it is at the date of this Agreement, or at any time after that date becomes, public knowledge through no fault of that Party, provided that in doing so that Party does not disclose any part of that Confidential Information which is not public knowledge.
10.3. The provisions of this Clause 10 shall continue in force in accordance with their terms, notwithstanding the termination of this Agreement for any reason.

11. Intellectual Property Rights
11.1. No Intellectual Property Rights transfer from any Party to any other Party under this Agreement. Without limitation, the Service Provider retains ownership of any and all Intellectual Property Rights in The System and which may subsist in the provision of the Services as provided by the Service Provider.
11.2. In consideration of the Service Commissioners' payment of the Fees, the Service Provider grants to the Service Commissioner a non-exclusive, non-transferable licence to use The System at the Locations for data entry purposes during the Term and only in accordance with the terms and conditions of this Agreement;
11.3. The Service Commissioner shall retain ownership and Intellectual Property Rights in:
11.3.1. any Services developed on The System that the Service Commissioner inputs into The System during the Term; and
11.3.2. any outputs created under this Agreement from data inputted by the Service Commissioner.
11.4. The Service Provider warrants to the Service Commissioner that the use of The System by the Service Commissioner in accordance with the terms and conditions of this Agreement shall not infringe the rights of any third party.

12. Termination
12.1. The Service Commissioner may terminate this Agreement by giving to the Service Provider not less than 30 days' written notice.
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12.2. In the event that the Service Commissioner commits a material breach of any of the terms and conditions of this Agreement the following provisions shall apply:
12.2.1. if the breach is capable of being remedied, the Service Provider shall give written notice to the Service Commissioner requiring the breach to be rectified;

12.2.2. if the Service Commissioner fails to rectify a breach notified to it pursuant to clause 12.2.1 within 20 Business Days then the Service Provider may terminate this Agreement at its sole discretion; and
12.2.3. if the breach is not capable of being remedied, the Service Provider may terminate this Agreement by issuing written notice with immediate effect.
12.3. In the event that the Service Provider commits any breach of any of the terms and conditions of this Agreement by failing to provide the Services to the required Service Levels or commit any other breach of this Agreement, the following provisions shall apply:
12.3.1. if the breach is capable of being remedied, the Service Commissioner may give written notice to the Service Provider requiring the Service Provider to rectify the breach;
12.3.2. if the Service Provider fails to rectify a breach notified to it pursuant to clause 12.3.1 within 20 Business Days then the Service Commissioner may terminate this Agreement at its sole discretion;
12.3.3. if the breach is not capable of being remedied, the Service Commissioner may terminate this Agreement by issuing written notice with immediate effect.
12.4. The Service Commissioner may forthwith terminate this Agreement by giving written notice to the Service Provider if:
12.4.1. an encumbrancer takes possession, or where the Service Provider is a company, a receiver is appointed, of any of the property or assets of the Service Provider;
12.4.2. the Service Provider makes any voluntary arrangement with its creditors or, being a company, becomes subject to an administration order (within the meaning of the Insolvency Act 1986);
12.4.3. the Service Provider, being an individual or firm, has a bankruptcy order made against it or, being a company, goes into liquidation (except for the purposes of bona fide amalgamation or re-construction and in such a manner that the company resulting therefrom effectively agrees to be bound by or assume the obligations imposed on the Service Provider under this Agreement);
12.4.4. anything analogous to any of the foregoing under the law of any jurisdiction occurs in relation to the Service Provider; or
12.4.5. the Service Provider ceases, or threatens to cease, to carry on business.
12.5. The Service Provider may forthwith terminate this Agreement by giving written notice to the Service Commissioner if:
12.5.1. an encumbrancer takes possession or where a Service Commissioner is a company, a receiver is appointed, of any of the assets of that Service Commissioner;
12.5.2. a Service Commissioner makes any voluntary arrangements with its creditors or, being a company, becomes subject to an administration order within the meaning of the Insolvency Act 1986;
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12.5.3. a Service Commissioner goes into liquidation (except for the purposes of bona fide amalgamation or re-construction and in such a manner that the company therefrom effectively agrees to be bound by or assume the obligations imposed by the individual Service Commissioner under this Agreement;

12.5.4. anything analogous to any of the foregoing under the law of any jurisdiction occurs in relation to the Service Commissioner; or
12.5.5. the Service Commissioner ceases, or threatens to cease, to carry on business.
12.6. The Service Commissioner shall have the right to forthwith terminate this Agreement by giving written notice to the Service Provider in the event that the Service Provider fails:
12.6.1. to meet the Daily Service Level for 20 consecutive Business Days;
12.6.2. to meet the Monthly Service Level for any two months during the Term.
12.7. The Service Provider may terminate this Agreement forthwith by giving written notice to the Service Commissioner if any sum owing to the Service Provider by the Service Commissioner has not been paid within 30 days of the due date for payment, and the Service Provider has given at least 10 days' notice to the Service Commissioner of the breach and specifying the remedy, and the Service Commissioner has failed to remedy the breach within the required notice period. The right to terminate this Agreement given by this Clause 12 shall not prejudice any other right or remedy of any Party in respect of the breach concerned (if any) or any other breach.

13. Post-Termination
13.1. Upon the termination of this Agreement for any reason:
13.1.1. any sum owing by a Party to any other Party under any of the provisions of this Agreement shall become immediately due and payable;
13.1.2. any rights or obligations to which any of the Parties to this Agreement may be entitled or be subject before its termination shall remain in full force and effect where they are expressly stated to survive such termination;
13.1.3. termination shall not affect or prejudice any right to damages or other remedy which the terminating Party may have in respect of the event giving rise to the termination or any other right to damages or other remedy which either Party may have in respect of any breach of this Agreement which existed at or before the date of termination;
13.1.4. subject as provided in this Clause 13, and except in respect of any accrued rights, none of the Parties shall be under any further obligation to the other save as the law shall allow;
13.1.5. each Party shall return all documents, materials and items provided to it for the purposes of this Agreement to the Party that owns such documents, materials and/or items; and
13.1.6. the Parties shall (except to the extent referred to in Clause 10) forthwith cease to use, either directly or indirectly, any Confidential Information, and shall forthwith return to the other Parties any documents in its possession or control which contain or record any Confidential Information except for one confidential copy which may be retained with the respective Party’s confidential files to enable that Party to ensure that it complies with any ongoing obligation or as obligated by the operation of law.
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13.2. Upon termination or expiry of this Agreement, the Service Commissioner shall be permitted to access and use any data collected on The System up to and including the date of expiry or termination of this Agreement and shall promptly (and at most within 90 days of termination or expiry) extract all required data from The System. Following such period, it may be deleted by the Service Provider in accordance with best industry practices and within the constraints of the requirements of the GDPR, and the Data Protection Act 2018.

14. Liability

14.1. The Service Provider shall indemnify and hold harmless the Service Commissioner, its sub-contractors, agents and employees from and against any and all claims, costs and liabilities howsoever arising and of whatsoever nature and whether in contract or in tort, including injury to or death of any person or persons or loss of or damage to any property suffered or incurred by the Service Commissioner arising out of or in respect of (1) actual or alleged infringement of a third party's intellectual property rights, (2) any breach by the Service Provider of its obligations under clause 10 of this Agreement, and (3) any breach of the Service Provider's obligations under clause 21 of this Agreement.

14.2. Except as expressly provided in this Agreement, the Service Provider and the Service Commissioner shall not be liable or responsible to the other in contract, tort or otherwise (including any liability for negligence) for:

14.2.1. any loss of revenue, business, contracts, anticipated savings or profits;

14.2.2. any loss of use of facilities; or

14.2.3. any special indirect or consequential loss howsoever arising.

14.3. For the purposes of sub-Clause 14.2.1 "anticipated savings" means any expense which a Party expects to avoid incurring or to incur in a lesser amount than would otherwise have been the case by reason of the use of the Services provided by the Service Provider under this Agreement.

14.4. Subject to clauses 14.2 and 14.5, the Service Commissioners' total aggregate liability to the Service Provider in respect of all causes of action arising out of or in connection with this Agreement whether for breach of contract, strict liability, tort (including negligence, misrepresentation or otherwise) shall not exceed a sum equivalent to the Fees.

14.5. Nothing in this Agreement shall limit or exclude any Party's liability for death or personal injury from its negligence, for fraud or fraudulent misrepresentation or for any other liability the exclusion or limitation of which is not permitted by English law.

15. Force Majeure

None of the Parties to this Agreement shall be liable for any failure or delay in performing their obligations where such failure or delay results from any cause that is beyond the reasonable control of that Party. Such causes include, but are not limited to: power failure, Internet Service Provider failure, industrial action, civil unrest, fire, flood, storms, earthquakes, acts of terrorism, acts of war, governmental action or any other event that is beyond the control of the Party in question. Where such a Force Majeure event occurs for a period exceeding 60 days, then the Parties may determine this Agreement by giving 7 Business Days' notice in writing.

16. Nature of the Agreement

16.1. This Agreement is personal to the Parties and no Party may assign, mortgage, or charge any of its rights hereunder, or sub-contract or otherwise delegate any of its obligations hereunder, except with the written consent of the other Party, such consent not to be

unreasonably withheld or delayed.

16.2. This Agreement contains the entire agreement between the Parties with respect to its subject matter and may not be modified except by an instrument in writing signed by the duly authorised representatives of the Parties.

16.3. Each Party acknowledges that, in entering into this Agreement, it does not rely on any representation, warranty or other provision except as expressly provided in this Agreement.

16.4. No failure or delay by a Party in exercising any of its rights under this Agreement shall be deemed to be a waiver of that right, and no waiver by a Party of a breach of any provision of this Agreement shall be deemed to be a waiver of any subsequent breach of the same or any other provision.

16.5. Subject to the provisions of Clause 11, at any time after the date hereof each of the Parties shall, at the request and cost of the other Party, execute or procure the execution of such documents and do or procure the doing of such acts and things as the Party so requiring may reasonably require for the purpose of giving to the Party so requiring the full benefit of all the provisions of this Agreement.

16.6. No term of this Agreement is enforceable under the Contracts (Rights of Third Parties) Act 1999 by a person who is not a party to this Agreement.

17. Severance

The Parties agree that, in the event that one or more of the provisions of this Agreement is found to be unlawful, invalid or otherwise unenforceable, that those provisions shall be deemed severed from the remainder of this Agreement. The remainder of this Agreement shall be valid and enforceable.

18. Relationship of the Parties

18.1. Nothing in this Agreement shall constitute, or be deemed to constitute, a partnership between the Parties or, except as expressly provided, shall it constitute, or be deemed to constitute an agency of any other Party for any purpose.

18.2. Subject to any express provisions to the contrary in this Agreement, a Party shall have no right or authority to, and shall not do any act, enter into any contract, make any representation, give any warranty, incur any liability, assume any obligation, whether express or implied, of any kind on behalf of any other Party or bind any other Party in any way.

19. Notices

19.1. All notices under this Agreement shall be in writing and be deemed duly given if signed by, or on behalf of, a duly authorised officer of the Party giving the notice.

19.2. Notices shall be deemed to have been duly given:

19.2.1. when delivered, if delivered by courier or other messenger (including registered mail) during normal business hours of the recipient; or
19.2.2. when sent, if transmitted by facsimile and a successful transmission report is generated;
19.2.3. when sent, if transmitted by email, when a read receipt is returned to the sender; or
19.2.4. on the fifth business day following mailing, if mailed by national ordinary mail, PharmOutcomes/Outcomes4Health Service Level Agreement V5 14
postage prepaid
when such notices are addressed to the most recent address, e-mail address, or facsimile number notified to the other Party.

20. Anti-Corruption
20.1. Each Party acknowledges that the other Parties are committed to eliminating all risk of bribery and corruption in their business relationships.
20.2. Each Party acknowledges and agrees that the other Party shall not be under any obligation to carry out any action or make any omission under this Agreement to the extent that it reasonably believes it would be in breach of any Anti-Corruption Legislation.
20.3. Each Party acknowledges and agrees that neither it nor any third party has breached any Anti-Corruption Legislation in order for the other Party to enter into this Agreement.
20.4. Each Party warrants and undertakes that:
20.4.1. it shall not engage in any activity, practice or conduct which would constitute an offence under sections 1, 2 or 6 of the Bribery Act 2010 or is otherwise contrary to any Anti-Corruption Legislation;
20.4.2. it has, and shall maintain in place, Adequate Procedures designed to prevent any Associated Person from undertaking any conduct that would give rise to an offence under section 7 of the Bribery Act 2010;
20.4.3. it, and each of its employees, directors, officers, subcontractors, agents and representatives that shall do anything on its behalf in relation to its obligations under this Agreement, has not taken, and shall not take, in the name of, for the account of or on behalf of any other Party, any actions in furtherance of (and it has not omitted to and shall not omit to take any action preventing): (i) an offer, payment, gift, promise to pay or give, or authorisation of the payment or giving of any money or anything else of value to any public official or to any other person or entity or (ii) the request for, agreement to or acceptance of any payment, gift, money or anything else of value, in each case, which constitutes a breach of any Anti-Corruption Legislation;
20.4.4. it shall keep accurate and detailed books, accounts, and records on all business activity conducted pursuant to this Agreement; and
20.4.5. from time to time, at the reasonable request of any other Party, it shall confirm in writing that it has complied with its undertakings under sub-clauses 20.4.1 to 20.4.4 above and shall provide access to such people and/or information reasonably requested by the other Party in support of such compliance.
20.5. Breach of any of the undertakings in this clause shall be deemed to be a material breach of this Agreement.

20.6. Where a Party reasonably believes that another Party is in breach of its obligations in sub-clause 20.4, upon request by such Party in writing (the "Requesting Party"), the other Party shall make available such people, books, accounts, records and other documentation relevant to its business activities conducted pursuant to this Agreement for an audit to be performed by a recognised independent firm of accountants (the “Auditor”) designated by the Requesting Party to the extent relevant to that breach. The Auditor shall provide to the Requesting Party only information obtained from such review that relates to the possible breach. The costs of such audit shall be borne by the Requesting Party save where the Auditor confirms that the other Party is in breach of its obligations, in which case, the other Party shall bear all costs.
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21. Data Protection
21.1. The terms of this Agreement are to apply to all processing of Personal Data carried out for the Commissioner by the Service Provider and to all Personal Data held by the Service Provider in relation to all such processing whether such Personal Data is held at the date of the Agreement or received afterwards. The terms of this agreement supersede any other arrangement, understanding or agreement made between the parties at any time relating to protection of Personal Data.
21.2. The Service Provider has appointed a Data Protection Officer (DPO) who is a qualified GDPR Practitioner, who has sufficient authority to act independently and has been given the necessary resources and access to information to allow them to exercise their responsibilities. The DPO can be contacted via dpo@phpartnership.com.
21.3. The Service Provider shall, to the extent that it processes any Personal Data in connection with this Agreement:
21.3.1. act only on written instructions from the data controller responsible for inputting the personal data in relation to its processing of the Personal Data;
21.3.2. in a manner consistent with Data Protection Legislation and with any guidance issued by the UK Information Commissioner, implement appropriate technical and organisational measures to safeguard the Data from unauthorised or unlawful Processing or accidental loss, destruction or damage, and that having regard to the state of technological development and the cost of implementing any measures, such measures shall ensure a level of security appropriate to the harm that might result from unauthorised or unlawful processing or accidental loss, destruction or damage and to the nature of the Data to be protected.
21.3.3. in furtherance of its obligations under 21.3.2 above implement and maintain the Security Measures listed in Clause 29;
21.3.4. not do or omit to do anything which causes the Service Provider to breach the Data Protection Legislation or any other law or contravene the terms of any registration, notification or authorisation of the Service Commissioner or any Service User that has provided any personal data under Data Protection Legislation;
21.3.5. if so requested by the Data Controller, supply details of the technical and organisational systems in place to safeguard the security of Personal Data held and to prevent unauthorised access;

21.3.6. take reasonable steps to ensure the reliability of all of its personnel (whether employees or contractors) that may have access to the personal data and to ensure that they are adequately trained in the good handling of personal data;
21.3.7. ensure that each of its employees, agents and subcontractors are made aware of its obligations under this agreement with regard to the security and protection of the Personal Data and shall require that they enter into binding obligations with the Service Provider in order to maintain the levels of security and protection provided for in this agreement;
21.3.8. not divulge Personal Data whether directly or indirectly to any person, firm or company or otherwise without the express prior written consent of the relevant Data Controller except to those of its employees, agents and subcontractors who are engaged in the Processing of the Data and are subject to the binding obligations referred to in clause 21.3.7 or except as may be required by any law or regulation;
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21.3.9. treat Personal Data as the confidential information of the Service Commissioner or System User as appropriate;
21.3.10. allow the Service Commissioner or its representatives reasonable access and assistance in order to ascertain compliance with the terms of this agreement;
21.3.11. use and retain Personal Data provided by the Service Commissioner only for the purposes of fulfilling its obligations under this Agreement;
21.3.12. not transfer Personal Data outside the United Kingdom without the prior written consent of the Service Commissioner (which consent may be given on such terms as the Service Commissioner may in their absolute discretion prescribe) and, where the Commissioner consents to such a transfer, to comply with the obligations of a Data Controller under the Eighth Data Protection Principle set out in Schedule 1 of the Act by providing an adequate level of protection to any Personal Data that is transferred and subsequently the restrictions imposed by the GDPR; and
21.3.13. where consent has been granted pursuant to clause 21.3.12 personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.
21.4. The Service Provider shall comply at all times with the GDPR, and the Data Protection Act 2018 and shall not perform its obligations under this Agreement or any other agreement or arrangement with the Data Controller in such a way as to cause the Service Commissioner to breach any of its applicable obligations under the Legislation.
21.5. The Service Provider agrees to comply with any reasonable measures required by the Service Commissioner to ensure that its obligations under this Agreement are satisfactorily performed in accordance with all applicable legislation from time to time in force and any best practice guidance issued by the ICO.
21.6. The Service Provider shall assist the relevant Data Controller promptly with
21.6.1. all subject access requests which may be received from individuals whose personal data the Service Provider is processing for the relevant Data Controller.
21.6.2. any complaint or request relating to the Data Controller’s obligations the GDPR and the Data Protection Act 2018.

21.7. The Service Provider shall notify the Data Controller immediately it becomes aware of:
21.7.1. any unauthorised or unlawful processing, loss of, or damage to or destruction of any of the Personal Data; or
21.7.2. any advance in technology or methods of working which mean that the Service Provider should revise the security measures set out in Clause29.
21.8. The Service Provider shall promptly amend, transfer or delete any personal data that it is processing for the relevant Data Controller if the relevant Data Controller by writing requires the Service Provider to do so.
21.9. The Service Provider shall notify the relevant Data Controller immediately of all communications the Service Provider receives from any person which suggests non-compliance with the GDPR and the Data Protection Act 2018 and the Service Provider shall not do anything or enter into any communication about it unless the relevant Data Controller expressly authorises the Service Provider to do so.
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21.10. The service provider shall co-operate with supervisory authorities on request, including the ICO.
21.11. On reasonable prior notice the Service Provider shall permit persons authorised by the Service Commissioner to enter into any premises on which the Personal Data provided by the Service Commissioner to the Service Provider is processed and to inspect the Service Provider's relevant facilities, equipment, documents and electronic data relating to the processing of the Service Commissioner's Personal Data. The requirement to give notice shall not apply if the Data Controller believes that the Data Processor is in breach of any of its obligations under this Agreement.
21.12. The provisions of this Clause 21 shall apply during the continuance of the Contract and indefinitely after its expiry or termination.

22. Counterparts
This Agreement may be executed in any number of counterparts, each of which when executed shall constitute a duplicate original, but all the counterparts shall together constitute the one agreement.

23. Publicity
A Party shall obtain written approval from the other Party prior to making any press release or public statement or announcements concerning the provision of the Services or any ancillary matter, where the other party is named. Any such required announcement shall, in any event, be issued only after prior consultation with the other Parties as to its contents.

24. Law and Jurisdiction
24.1. This Agreement (including any non-contractual matters and obligations arising therefrom or associated therewith) shall be governed by, and construed in accordance with, the laws of England and Wales.
24.2. Any dispute, controversy, proceedings or claim between the Parties relating to this Agreement (including any non-contractual matters and obligations arising

therefrom or associated therewith) shall fall within the jurisdiction of the courts of England and Wales.

25. Anti-Discrimination
25.1. The Service Provider shall not unlawfully discriminate within the meaning and scope of any law, enactment, order, or regulation relating to discrimination (whether in age, race, gender, religion, disability, sexual orientation or otherwise) in employment.
25.2. The Service Provider shall take all reasonable steps to secure the observance of clause 25.1 by all servants, employees or agents of the Service Provider and all suppliers and sub-contractors employed in performance of this agreement.

26. Freedom of Information
26.1. Where the Service Commissioner is subject to the Freedom of Information Act 2000 ("the Act"), it may be required to disclose information forming part of the Agreement to anyone who makes a reasonable request as part of the Service Commissioner's duties under the Act. It is acknowledged that the Service Commissioner has absolute discretion to apply or not to apply any exemptions under the Act.
26.2. The Service Provider shall assist and cooperate with the Service Commissioner (at the Service Provider's reasonable expense) to enable the Service Commissioner to comply with the information disclosure requirements under the Act and in so doing shall comply
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with any timescale notified to it by the Service Commissioner.

27. Data Migration
The Service Provider shall at no additional charge provide such reasonably requested assistance to the Service Commissioner in identifying validation criteria to facilitate successful migration of the Data identified by the Service Commissioner onto an external system.

28. Service Commissioner Data
28.1. The Service Provider shall not store, copy, disclose, or use the Service Commissioner Data except as necessary for the performance by the Service Provider of its obligations under this Contract or as otherwise expressly authorised in writing by the Service Commissioner.
28.2. To the extent that Service Commissioner Data is held, the Service Provider shall supply that Service Commissioner Data to the Service Commissioner as requested by the Service Commissioner in the format requested.
28.3. The Service Provider shall take responsibility for preserving the integrity of Service Commissioner Data that it holds and preventing the corruption or loss of such Service Commissioner Data.
28.4. The Service Provider shall ensure that any system on which the Service Provider holds any Service Commissioner Data, including back-up data, is a secure system that complies with its security policy.

28.5. If at any time the Service Provider suspects or has reason to believe that Service Commissioner Data has or may become corrupted, lost or sufficiently degraded in any way for any reason, then the Service Provider shall notify the Service Commissioner immediately and inform the Service Commissioner of the remedial action the Service Provider proposes to take.

29. Security
29.1. The following Security Measures shall be maintained by the Service Provider:
29.1.1. The Service Provider shall ensure that in respect of all Personal Data it receives from or processes on behalf of the Data Controller it maintains security measures to a standard appropriate to:
29.1.1.1. the harm that might result from unlawful or unauthorised processing or accidental loss, damage or destruction of the Personal Data; and
29.1.1.2. the nature of the Personal Data
29.2. In particular the Service Provider shall:
29.2.1. have in place and comply with a security policy which:
29.2.1.1. defines security needs based on a risk assessment;
29.2.1.2. allocates responsibility for implementing the policy to a specific individual or members of a team;
29.2.1.3. is disseminated to all relevant staff; and
29.2.1.4. provides a mechanism for feedback and review.
29.2.2. ensure that The System is hosted in secure data centres;
29.2.3. ensure that The System is tested regularly to ensure that it continues to meet the requirements of Clause 29.1 and ISO27001 standards. Any changes to the PharmOutcomes/Outcomes4Health Service Level Agreement V5 19
hosting centre shall be to no lesser standard of security for The System than originally agreed and shall be notified in advance to the Service Commissioner unless the delay involved in doing so would compromise the security of The System;
29.2.4. ensure that appropriate security safeguards and virus protection are in place to protect the hardware and software which is used in processing the Personal Data in accordance with best industry practice;
29.2.5. prevent unauthorised access to Personal Data;
29.2.6. ensure its storage of Personal Data conforms with best industry practice such that the media on which Personal Data is recorded are stored in secure locations and access by personnel to Personal Data is strictly monitored and controlled;
29.2.7. have secure methods in place for the transfer of Personal Data whether in physical form or electronic form (for instance, by using encryption);
29.2.8. put password protection on computer systems on which Personal Data is stored and ensure that only authorised personnel are given details of the password;
29.2.9. take reasonable steps to ensure the reliability of employees or other individuals who have access to the Personal Data;
29.2.10. ensure that any employees or other individuals required to access the Personal Data are informed of the confidential nature of the Personal Data and comply with the obligations set out in this agreement;

29.2.11. ensure that none of the employees or other individuals who have access to the Personal Data publish, disclose or divulge any of the Personal Data to any third party unless directed in writing to do so by the Data Controller;
29.2.12. have in place methods for detecting and dealing with breaches of security (including loss, damage or destruction of Personal Data) including:
29.2.12.1. the ability to identify which individuals worked with specific Personal Data;
29.2.12.2. having an appropriate procedure for backing up and storing back-ups separately from originals;
29.2.12.3. notifying the Data Controller as soon as any security breach occurs;
29.2.13. have a secure procedure for backing up and storing back-ups separately from originals;
29.2.14. have a secure method of disposal of unwanted Personal Data including for back-ups, disks and redundant equipment; and
29.2.15. adopt such organisational, operational and technological processes and procedures as are required to comply with the requirements of ISO27001:2013 as appropriate to the Services provided to the Data Controller.
29.3. The Service Provider shall obtain and maintain the following security standards for the duration of this agreement:
29.3.1. NHS Information Governance Toolkit at Level 3;
29.3.2. Online Security Certificates with credible and recognised authority; and
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29.3.3. System Infrastructure Management accredited to ISO27001:2013.
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Service Levels

The core hours of business for the Service Provider are 08:30 to 18:00 on each Business Day.

The Service Provider undertakes to provide service availability for Service Users and Service Commissioners according to the following minimum standards, together known as the "Service Levels":

1. a maximum unavailability of 2 hours of each Month during the Term ("Monthly Service Level"); and

2. a maximum unavailability of ½ hour on any one Business Day during the Term ("Daily Service Level").

Response Times

Additional undertakings by the Service Provider regarding response times	**Response Times**
Priority	
Initial Response to Service Commissioner requests by telephone or through the Messaging Service on the Help page of The System for support.	10 minutes
A Service Failure which, in the reasonable opinion of the Service Commissioner, constitutes a loss of The Service which prevents a large group of End Users from working, or has a critical impact on the activities of the Service Commissioner.	30 Minutes
A Service Failure which, in the reasonable opinion of the Service Commissioner, has the potential to have a major adverse impact on the activities of the Service Commissioner which can be reduced to a moderate adverse impact due to the availability of a contingency.	1 hour
A Service Failure which, in the reasonable opinion of the Service Commissioner, has the potential to have a minor adverse impact on the provision of The Service to End Users.	1 Business Day
A Service Failure comprising a flaw which is cosmetic and, as such, does not undermine the Service User's confidence in The Services.	5 Business Days